

NEXIUM®

Esomeprazole magnesium trihydrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions people ask about Nexium. It does not contain all the information that is known about Nexium.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking Nexium against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Nexium is used for

Reflux Oesophagitis

Nexium is taken to treat reflux oesophagitis. This can be caused by "washing back" (reflux) of food and acid from the stomach into the food pipe (oesophagus).

Reflux can cause a burning sensation in the chest rising up to the throat, also known as heartburn.

Nexium is also taken to help stop reflux oesophagitis coming back or relapsing.

Upper gastrointestinal symptoms associated with non-steroidal anti-inflammatory drugs (NSAIDs) therapy

Nexium is taken to treat the symptoms of pain or discomfort, in the stomach caused by NSAIDs, a type of medicine for pain or inflammation.

Nexium is also taken to help heal and prevent ulcers caused by NSAIDs.

Peptic Ulcers Associated with Helicobacter pylori Infection

Most people who have a peptic (gastric and duodenal) ulcer also have a bacterium called *Helicobacter pylori* in their stomach.

Depending on the position of the ulcer it is called a gastric or duodenal ulcer. A gastric ulcer occurs in the stomach. A duodenal ulcer occurs in the duodenum which is the tube leading out from the stomach.

If you have a peptic ulcer, your doctor will prescribe Nexium with antibiotics. When Nexium and antibiotics are taken together, they work to kill the bacterium and let your ulcer heal. You may need further treatment with antibiotics.

Zollinger-Ellison Syndrome

Nexium is also used to treat a rare condition called Zollinger-Ellison syndrome, where the stomach produces large amounts of acid, much more than in ulcers or reflux disease.

Bleeding Peptic Ulcers

When peptic ulcers become severe enough, they start to bleed. You may receive treatment injected into your veins initially. This treatment may be followed with Nexium tablets or granules prescribed by your doctor for a longer period of time. This is to help your ulcer/s to heal.

How Nexium works

Nexium is a type of medicine called a proton-pump inhibitor. It works by decreasing the amount of acid made by the stomach, to give relief of symptoms and allow healing to take place. This does not stop food being digested in the normal way.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

Ask your doctor if you want more information.

Your doctor may have prescribed Nexium for another reason.

There is no evidence that Nexium is addictive.

Before you take Nexium

When you must not take it

Do not take Nexium if you have allergies to:

- esomeprazole or any ingredient listed at the end of this leaflet.
- any medicines containing a proton-pump inhibitor.

How to take Nexium

Follow all directions given to you by your doctor and pharmacist carefully.

These instructions may differ from the information contained in this leaflet

If you do not understand the directions on the label, ask your doctor or pharmacist for help.

How to take it

Nexium is available as tablets and as granules for suspension in sachets.

Nexium Tablets

Take one Nexium tablet each day, unless your doctor has told you otherwise.

The dose of Nexium tablets is usually 20 mg or 40 mg a day depending on what condition you are being treated for and how severe it is.

Swallow Nexium tablets whole with a glass of water. Do not crush or chew the tablets.

If the tablets are chewed or crushed they will not work properly.

If you have difficulty swallowing the tablets:

1. Place the tablet in half a glass of non-carbonated water. Mineral water or other liquids are not suitable
2. Gently mix the tablet and water by stirring, taking care not to crush the tablet
3. Stir until the tablet dissolves into little pellets
4. Drink the liquid with the pellets immediately, or within 30 minutes. Do not chew the pellets
5. Rinse the glass with half a glass of water and drink.

If you cannot swallow at all, follow steps 1-3 above to disperse the tablets and administer the liquid and pellets through a gastric tube.

Nexium Sachets

Nexium sachets are usually used for children or adults who have trouble

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take NEXIUM if you are also taking atazanavir or cilostazol.

Please check with your doctor or pharmacist if you are taking these medicines. These medicines will be affected by Nexium.

Nexium is not approved for use in children younger than 1 year of age.

There is no specific information about use in children younger than 1 year of age, so Nexium is not recommended in these patients.

Do not take Nexium after the use by (expiry) date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to take it

You must tell your doctor if you have:

- allergies to any other medicines, foods, dyes or preservatives.
- any problems with your liver
- severe kidney problems
- any other medical conditions

Do not take Nexium if you are pregnant or breastfeeding unless your doctor says so. Ask your doctor about the risks and benefits involved.

It is not known if it is safe for you to take Nexium while you are pregnant. It may affect your baby.

It is not known if your baby can take in Nexium from breast milk if you are breastfeeding.

Taking other medicines

Do not take Nexium if you are taking the following medicines:

- atazanavir, a medicine used to treat Human Immunodeficiency Virus (HIV)
- cilostazol, a medicine used to treat intermittent claudication.

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Nexium. These include:

- medicines used to treat fungal infections such as ketoconazole, itraconazole and voriconazole
- cisapride
- diazepam, a medicine used to treat anxiety and some other conditions
- phenytoin, a medicine used to treat epilepsy
- medicines used to treat depression such as citalopram, clomipramine and imipramine
- St John's wort, a herbal remedy used to treat mood disorders
- medicines used to treat bacterial infections such as clarithromycin and rifampicin
- warfarin, a medicine used to prevent blood clots
- medicines for HIV treatment such as nelfinavir
- digoxin, a medicine used to treat heart conditions

These medicines may be affected by Nexium or may affect how well it works. You may need different amounts of your medicine or you may need to take different medicines. Your doctor can tell you what to do if you are taking any other medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Nexium.

If you have not told your doctor about any of these things, tell them before you take Nexium.

swallowing tablets. The dose of Nexium sachets is 10 to 20 mg a day depending on what condition is being treated and how severe it is.

The granules in Nexium sachets should be dispersed as follows in non-carbonated water (mineral water is not suitable) before being taken:

1. For a 10 mg dose empty the contents of a 10 mg sachet into a glass containing 15 mL of water. For a 20 mg dose empty the contents of two 10 mg sachets into a glass containing 30 mL of water.
2. Stir the contents and leave for a few minutes to thicken.
3. Stir again and drink within 30 minutes.
4. If any material remains after drinking, add more water, stir and drink immediately.

For patients who cannot swallow, Nexium granules for oral suspension can be administered via a large syringe through a nasogastric or gastric tube:

1. For a 10 mg dose add the contents of a 10 mg sachet to a syringe containing 15 mL of water. For a 20 mg dose add the contents of two 10 mg sachets to a syringe containing 30 mL of water.
2. Immediately shake the syringe and leave for a few minutes to thicken.
3. Shake the syringe and inject through the nasogastric or gastric tube within 30 minutes.
4. Refill the syringe with 15 mL of water, then shake and flush any remaining contents from the nasogastric or gastric tube into the stomach.

Do not crush or chew the pellets in the suspension.

If the pellets are chewed or crushed they will not work properly.

Take Nexium at about the same time each day.

Keeping a regular time for taking Nexium will help to remind you to take it.

Keep taking Nexium for as long as your doctor recommends.

In most patients, Nexium relieves symptoms rapidly and healing is usually complete within 4 weeks. Continue taking Nexium for as long as your doctor tells you to.

Nexium can be taken with food or on an empty stomach.

If you forget to take it

If you forget to take a dose, take it as soon as you remember, and then go back to taking it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

Taking too much (overdose)

Telephone your doctor or the Poisons Information Centre (13 11 26) or go to Accident and Emergency at your nearest hospital immediately if you think that you or anyone else may have taken too many Nexium. Do this even if there are no signs of discomfort or poisoning.

While you are taking NEXIUM

Things you must do

Take Nexium exactly as your doctor has prescribed.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking Nexium.

Tell all doctors, dentists and pharmacists who are treating you that you are taking Nexium.

Tell your doctor if you become pregnant while you are taking Nexium.

Tell your doctor if your symptoms return.

Although Nexium can heal ulcers successfully, it may not prevent them recurring at a later date.

If you need to have any medical tests while you are taking Nexium, tell your doctor.

It may affect the results of some tests.

Things you must not do

Do not take it to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Nexium.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- nausea or vomiting
- constipation
- diarrhoea
- headache
- wind
- stomach pain
- skin rash, itchy skin
- dizziness

- dry mouth.

These side effects are usually mild.

Tell your doctor immediately if you notice any of the following:

- blurred vision
- mood changes, confusion or depression
- muscle pain or weakness, joint pain
- increase in breast size (males)
- increased sweating
- changes in sleep patterns
- fever
- increased bruising
- "pins and needles"
- hair loss
- tremor
- blood in the urine

These side effects may require medical attention.

If you notice any of the following happen, tell your doctor immediately or go to Accident and Emergency at the nearest hospital:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- severe skin reaction which may include rash, itching, redness, blistering or peeling of the skin
- signs of liver inflammation including yellowing of the skin or eyes, feeling generally unwell, nausea, vomiting, loss of appetite.

These are very serious side effects. You may need urgent medical treatment or hospitalisation.

Occasionally, Nexium may be associated with changes in your liver or blood, which may require your doctor to do certain blood tests.

Tell your doctor if you think you have any of these effects or notice anything else that is making you feel unwell.

Some people may get other side effects while taking Nexium.

Other problems are more likely to arise from the condition itself rather than the treatment.

For this reason, contact your doctor immediately if you notice any of the following:

- pain or indigestion during treatment with Nexium
- you begin to vomit blood or food
- you pass black (blood-stained) motions.

After taking it

Storage

Keep your Nexium in the blister pack until it is time to take them.

If you take Nexium out of the blister pack it will not keep well.

Keep it in a cool, dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on a window sill.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking Nexium or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets you have left over.

Product description

What Nexium looks like

Tablets

Nexium 20 mg are light pink, oblong shaped tablets engraved 20 mg on one side and A / EH on the other.

Nexium 40 mg are pink, oblong shaped tablets engraved 40 mg on one side and A / EI on the other.

Nexium Granules for oral suspension

Nexium 10 mg granules for oral suspension are pale yellow fine granules (brownish granules may be visible) in a unit dose sachet.

Ingredients

Tablets

Each Nexium tablet contains esomeprazole magnesium trihydrate as the active ingredient equivalent to esomeprazole 20mg or 40mg;

plus,

- Glyceryl monostearate (E 471)
- Hydroxypropyl cellulose
- Hypromellose
- Magnesium stearate (E 572)
- Methacrylic acid copolymer
- Microcrystalline cellulose (E 460).
- Paraffin hard
- Macrogol 6000
- Polysorbate 80 (E 433)
- Crospovidone
- Sodium stearyl fumarate
- Purified talc (E 553(b))
- Titanium dioxide (E 171)
- Triethyl citrate
- Sugar spheres (maize starch and sucrose).

The tablets are coloured with iron oxide red CI77491 and/or iron oxide yellow CI77492

Nexium Granules for oral suspension

Each sachet of Nexium granules for oral suspension contains esomeprazole magnesium trihydrate as the active ingredient equivalent to esomeprazole 10mg; plus,

- glyceryl monostearate
- hydroxypropylcellulose

- hypromellose
- magnesium stearate
- methacrylic acid copolymer
- polysorbate 80
- talc
- triethyl citrate
- glucose - anhydrous
- xanthan gum
- crospovidone
- citric acid - anhydrous
- iron oxide yellow
- sugar spheres (maize starch and sucrose).

Nexium tablets and granules for oral suspension do not contain gluten.

Nexium tablets are available in blister packs of 7 or 30 tablets.

Nexium granules are available in packs containing 30 unit dose sachets.

Sponsor

AstraZeneca Pty Ltd

ABN 54 009 682 311

Alma Road

NORTH RYDE NSW 2113

This leaflet was prepared June 2010.

Australian Registration Number

Nexium 20 mg (blister) - 74133

Nexium 40 mg (blister) - 74134

Nexium 10 mg (sachet) - 135726

Non-marketed presentations

Nexium 20 mg (bottle) - 75726

Nexium 40 mg (bottle) - 75727

Trade Marks herein are the property of the AstraZeneca group

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Reflux can cause a burning sensation in the chest rising up to the throat, also known as heartburn.

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If you have a peptic ulcer, your doctor will prescribe Nexium with antibiotics. When Nexium and antibiotics are taken together, they work to kill the bacterium and let your ulcer heal. You may need further treatment with antibiotics.

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Your doctor may have prescribed Nexium for another reason.

There is no evidence that Nexium is addictive.

Before you take Nexium

When you must not take it

Do not take Nexium if you have allergies to:

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- any medicines containing a proton-pump inhibitor.

How to take Nexium

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If you do not understand the directions on the label, ask your doctor or pharmacist for help.

How to take it

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Nexium Tablets

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The dose of Nexium tablets is usually 20 mg or 40 mg a day depending on what condition you are being treated for and how severe it is.

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If the tablets are chewed or crushed they will not work properly.

If you have difficulty swallowing the tablets:

1. Place the tablet in half a glass of non-carbonated water. Mineral water or other liquids are not suitable
2. Gently mix the tablet and water by stirring, taking care not to crush the tablet
3. Stir until the tablet dissolves into little pellets
4. Drink the liquid with the pellets immediately, or within 30 minutes. Do not chew the pellets
5. Rinse the glass with half a glass of water and drink.

If you cannot swallow at all, follow steps 1-3 above to disperse the tablets and administer the liquid and pellets through a gastric tube.

Nexium Sachets

Nexium sachets are usually used for children or adults who have trouble

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

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There is no specific information about use in children younger than 1 year of age, so Nexium is not recommended in these patients.

Do not take Nexium after the use by (expiry) date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to take it

You must tell your doctor if you have:

- allergies to any other medicines, foods, dyes or preservatives.
- any problems with your liver
- severe kidney problems
- any other medical conditions

Do not take Nexium if you are pregnant or breastfeeding unless your doctor says so. Ask your doctor about the risks and benefits involved.

It is not known if it is safe for you to take Nexium while you are pregnant. It may affect your baby.

It is not known if your baby can take in Nexium from breast milk if you are breastfeeding.

Taking other medicines

Do not take Nexium if you are taking the following medicines:

- atazanavir, a medicine used to treat Human Immunodeficiency Virus (HIV)

- cilostazol, a medicine used to treat intermittent claudication.

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Nexium. These include:

- medicines used to treat fungal infections such as ketoconazole, itraconazole and voriconazole
- cisapride
- diazepam, a medicine used to treat anxiety and some other conditions
- phenytoin, a medicine used to treat epilepsy
- medicines used to treat depression such as citalopram, clomipramine and imipramine
- St John's wort, a herbal remedy used to treat mood disorders
- medicines used to treat bacterial infections such as clarithromycin and rifampicin
- warfarin, a medicine used to prevent blood clots
- medicines for HIV treatment such as nelfinavir
- digoxin, a medicine used to treat heart conditions
- methotrexate, a medicine used to treat arthritis and some types of cancer
- erlotinib or related medicines used to treat cancer.

These medicines may be affected by Nexium or may affect how well it works. You may need different amounts of your medicine or you may need to take different medicines. Your doctor can tell you what to do if you are taking any other medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Nexium.

If you have not told your doctor about any of these things, tell them before you take Nexium.

swallowing tablets. The dose of Nexium sachets is 10 to 20 mg a day depending on what condition is being treated and how severe it is.

The granules in Nexium sachets should be dispersed as follows in non-carbonated water (mineral water is not suitable) before being taken:

1. For a 10 mg dose empty the contents of a 10 mg sachet into a glass containing 15 mL of water. For a 20 mg dose empty the contents of two 10 mg sachets into a glass containing 30 mL of water.
2. Stir the contents and leave for a few minutes to thicken.
3. Stir again and drink within 30 minutes.
4. If any material remains after drinking, add more water, stir and drink immediately.

For patients who cannot swallow, Nexium granules for oral suspension can be administered via a large syringe through a nasogastric or gastric tube:

1. For a 10 mg dose add the contents of a 10 mg sachet to a syringe containing 15 mL of water. For a 20 mg dose add the contents of two 10 mg sachets to a syringe containing 30 mL of water.
2. Immediately shake the syringe and leave for a few minutes to thicken.
3. Shake the syringe and inject through the nasogastric or gastric tube within 30 minutes.
4. Refill the syringe with 15 mL of water, then shake and flush any remaining contents from the nasogastric or gastric tube into the stomach.

Do not crush or chew the pellets in the suspension.

If the pellets are chewed or crushed they will not work properly.

Take Nexium at about the same time each day.

Keeping a regular time for taking Nexium will help to remind you to take it.

Keep taking Nexium for as long as your doctor recommends.

In most patients, Nexium relieves symptoms rapidly and healing is usually complete within 4 weeks. Continue taking Nexium for as long as your doctor tells you to.

Nexium can be taken with food or on an empty stomach.

If you forget to take it

If you forget to take a dose, take it as soon as you remember, and then go back to taking it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

Taking too much (overdose)

Telephone your doctor or the Poisons Information Centre (13 11 26) or go to Accident and Emergency at your nearest hospital immediately if you think that you or anyone else may have taken too many Nexium. Do this even if there are no signs of discomfort or poisoning.

While you are taking NEXIUM

Things you must do

Take Nexium exactly as your doctor has prescribed.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking Nexium.

Tell all doctors, dentists and pharmacists who are treating you that you are taking Nexium.

Tell your doctor if you become pregnant while you are taking Nexium.

Tell your doctor if your symptoms return.

Although Nexium can heal ulcers successfully, it may not prevent them recurring at a later date.

If you need to have any medical tests while you are taking Nexium, tell your doctor.

It may affect the results of some tests.

Things you must not do

Do not take it to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Nexium.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- nausea or vomiting
- constipation
- diarrhoea
- headache
- wind
- stomach pain
- skin rash, itchy skin
- dizziness

- dry mouth.

These side effects are usually mild.

Tell your doctor immediately if you notice any of the following:

- blurred vision
- mood changes, confusion or depression
- muscle pain or weakness, joint pain
- increase in breast size (males)
- increased sweating
- changes in sleep patterns
- fever
- increased bruising
- "pins and needles"
- hair loss
- tremor
- blood in the urine

These side effects may require medical attention.

If you notice any of the following happen, tell your doctor immediately or go to Accident and Emergency at the nearest hospital:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- severe skin reaction which may include rash, itching, redness, blistering or peeling of the skin
- signs of liver inflammation including yellowing of the skin or eyes, feeling generally unwell, nausea, vomiting, loss of appetite.

These are very serious side effects. You may need urgent medical treatment or hospitalisation.

Occasionally, Nexium may be associated with changes in your liver or blood, which may require your doctor to do certain blood tests.

Tell your doctor if you think you have any of these effects or notice anything else that is making you feel unwell.

Some people may get other side effects while taking Nexium.

Other problems are more likely to arise from the condition itself rather than the treatment.

For this reason, contact your doctor immediately if you notice any of the following:

- pain or indigestion during treatment with Nexium
- you begin to vomit blood or food
- you pass black (blood-stained) motions.

After taking it

Storage

Keep your Nexium in the blister pack until it is time to take them.

If you take Nexium out of the blister pack it will not keep well.

Keep it in a cool, dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on a window sill.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking Nexium or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets you have left over.

Product description

What Nexium looks like

Tablets

Nexium 20 mg are light pink, oblong shaped tablets engraved 20 mg on one side and A / EH on the other.

Nexium 40 mg are pink, oblong shaped tablets engraved 40 mg on one side and A / EI on the other.

Nexium Granules for oral suspension

Nexium 10 mg granules for oral suspension are pale yellow fine granules (brownish granules may be visible) in a unit dose sachet.

Ingredients

Tablets

Each Nexium tablet contains esomeprazole magnesium trihydrate as the active ingredient equivalent to esomeprazole 20mg or 40mg;

plus,

- Glyceryl monostearate (E 471)
- Hydroxypropyl cellulose
- Hypromellose
- Magnesium stearate (E 572)
- Methacrylic acid copolymer
- Microcrystalline cellulose (E 460).
- Paraffin hard
- Macrogol 6000
- Polysorbate 80 (E 433)
- Crospovidone
- Sodium stearyl fumarate
- Purified talc (E 553(b))
- Titanium dioxide (E 171)
- Triethyl citrate
- Sugar spheres (maize starch and sucrose).

The tablets are coloured with iron oxide red CI77491 and/or iron oxide yellow CI77492

Nexium Granules for oral suspension

Each sachet of Nexium granules for oral suspension contains esomeprazole magnesium trihydrate as the active ingredient equivalent to esomeprazole 10mg; plus,

- glyceryl monostearate
- hydroxypropylcellulose

- hypromellose
- magnesium stearate
- methacrylic acid copolymer
- polysorbate 80
- talc
- triethyl citrate
- glucose - anhydrous
- xanthan gum
- crospovidone
- citric acid - anhydrous
- iron oxide yellow
- sugar spheres (maize starch and sucrose).

Nexium tablets and granules for oral suspension do not contain gluten.

Nexium tablets are available in blister packs of 7 or 30 tablets.

Nexium granules are available in packs containing 30 unit dose sachets.

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Nexium 20 mg (bottle) - 75726

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Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions people ask about Nexium. It does not contain all the information that is known about Nexium.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking Nexium against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Nexium is used for

Reflux Oesophagitis

Nexium is taken to treat reflux oesophagitis. This can be caused by "washing back" (reflux) of food and acid from the stomach into the food pipe (oesophagus).

Reflux can cause a burning sensation in the chest rising up to the throat, also known as heartburn.

Nexium is also taken to help stop reflux oesophagitis coming back or relapsing.

Upper gastrointestinal symptoms associated with non-steroidal anti-inflammatory drugs (NSAIDs) therapy

Nexium is taken to treat the symptoms of pain or discomfort, in the stomach caused by NSAIDs, a type of medicine for pain or inflammation.

Nexium is also taken to help heal and prevent ulcers caused by NSAIDs.

Peptic Ulcers Associated with *Helicobacter pylori* Infection

Most people who have a peptic (gastric and duodenal) ulcer also have a bacterium called *Helicobacter pylori* in their stomach.

Depending on the position of the ulcer it is called a gastric or duodenal ulcer. A gastric ulcer occurs in the stomach. A duodenal ulcer occurs in the duodenum which is the tube leading out from the stomach.

If you have a peptic ulcer, your doctor will prescribe Nexium with antibiotics. When Nexium and antibiotics are taken together, they work to kill the bacterium and let your ulcer heal. You may need further treatment with antibiotics.

Zollinger-Ellison Syndrome

Nexium is also used to treat a rare condition called Zollinger-Ellison syndrome, where the stomach produces large amounts of acid, much more than in ulcers or reflux disease.

Bleeding Peptic Ulcers

When peptic ulcers become severe enough, they start to bleed. You may receive treatment injected into your veins initially. This treatment may be followed with Nexium tablets or granules prescribed by your doctor for a longer period of time. This is to help your ulcer/s to heal.

How Nexium works

Nexium is a type of medicine called a proton-pump inhibitor. It works by decreasing the amount of acid made by the stomach, to give relief of symptoms and allow healing to take place. This does not stop food being digested in the normal way.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

Ask your doctor if you want more information.

Your doctor may have prescribed Nexium for another reason.

There is no evidence that Nexium is addictive.

Before you take Nexium

When you must not take it

Do not take Nexium if you have allergies to:

- esomeprazole or any ingredient listed at the end of this leaflet.
- any medicines containing a proton-pump inhibitor.

How to take Nexium

Follow all directions given to you by your doctor and pharmacist carefully.

These instructions may differ from the information contained in this leaflet

If you do not understand the directions on the label, ask your doctor or pharmacist for help.

How to take it

Nexium is available as tablets and as granules for suspension in sachets.

Nexium Tablets

Take one Nexium tablet each day, unless your doctor has told you otherwise.

The dose of Nexium tablets is usually 20 mg or 40 mg a day depending on what condition you are being treated for and how severe it is.

Swallow Nexium tablets whole with a glass of water. Do not crush or chew the tablets.

If the tablets are chewed or crushed they will not work properly.

If you have difficulty swallowing the tablets:

1. Place the tablet in half a glass of non-carbonated water. Mineral water or other liquids are not suitable
2. Gently mix the tablet and water by stirring, taking care not to crush the tablet
3. Stir until the tablet dissolves into little pellets
4. Drink the liquid with the pellets immediately, or within 30 minutes. Do not chew the pellets
5. Rinse the glass with half a glass of water and drink.

If you cannot swallow at all, follow steps 1-3 above to disperse the tablets and administer the liquid and pellets through a gastric tube.

Nexium Sachets

Nexium sachets are usually used for children or adults who have trouble

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take NEXIUM if you are also taking atazanavir or cilostazol.

Please check with your doctor or pharmacist if you are taking these medicines. These medicines will be affected by Nexium.

Nexium is not approved for use in children younger than 1 year of age.

There is no specific information about use in children younger than 1 year of age, so Nexium is not recommended in these patients.

Do not take Nexium after the use by (expiry) date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to take it

You must tell your doctor if you have:

- allergies to any other medicines, foods, dyes or preservatives.
- any problems with your liver
- severe kidney problems
- any other medical conditions

Do not take Nexium if you are pregnant or breastfeeding unless your doctor says so. Ask your doctor about the risks and benefits involved.

It is not known if it is safe for you to take Nexium while you are pregnant. It may affect your baby.

It is not known if your baby can take in Nexium from breast milk if you are breastfeeding.

Taking other medicines

Do not take Nexium if you are taking the following medicines:

- atazanavir and nelfinavir - medicines used to treat viral infections such as HIV

- cilostazol - a medicine used to treat intermittent claudication.

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Nexium. These include:

- ketoconazole, itraconazole and voriconazole - medicines used to treat fungal infections
- diazepam - a medicine used to treat anxiety and some other conditions
- phenytoin - a medicine used to treat epilepsy or fits
- citalopram, clomipramine and imipramine - medicines used to treat depression
- St John's Wort - a herbal remedy used to treat mood disorders
- clarithromycin and rifampicin - medicines used to treat bacterial infections
- warfarin - a medicine used to prevent blood clots
- digoxin - a medicine used to treat heart conditions
- methotrexate - a medicine used to treat arthritis and some types of cancer
- tacrolimus - a medicine used to assist in organ transplants
- erlotinib or related medicines used to treat cancer.

These medicines may be affected by Nexium or may affect how well it works. You may need different amounts of your medicine or you may need to take different medicines. Your doctor can tell you what to do if you are taking any other medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Nexium.

If you have not told your doctor about any of these things, tell them before you take Nexium.

swallowing tablets. The dose of Nexium sachets is 10 to 20 mg a day depending on what condition is being treated and how severe it is.

The granules in Nexium sachets should be dispersed as follows in non-carbonated water (mineral water is not suitable) before being taken:

1. For a 10 mg dose empty the contents of a 10 mg sachet into a glass containing 15 mL of water. For a 20 mg dose empty the contents of two 10 mg sachets into a glass containing 30 mL of water.
2. Stir the contents and leave for a few minutes to thicken.
3. Stir again and drink within 30 minutes.
4. If any material remains after drinking, add more water, stir and drink immediately.

For patients who cannot swallow, Nexium granules for oral suspension can be administered via a large syringe through a nasogastric or gastric tube:

1. For a 10 mg dose add the contents of a 10 mg sachet to a syringe containing 15 mL of water. For a 20 mg dose add the contents of two 10 mg sachets to a syringe containing 30 mL of water.
2. Immediately shake the syringe and leave for a few minutes to thicken.
3. Shake the syringe and inject through the nasogastric or gastric tube within 30 minutes.
4. Refill the syringe with 15 mL of water, then shake and flush any remaining contents from the nasogastric or gastric tube into the stomach.

Do not crush or chew the pellets in the suspension.

If the pellets are chewed or crushed they will not work properly.

Take Nexium at about the same time each day.

Keeping a regular time for taking Nexium will help to remind you to take it.

Keep taking Nexium for as long as your doctor recommends.

In most patients, Nexium relieves symptoms rapidly and healing is usually complete within 4 weeks. Continue taking Nexium for as long as your doctor tells you to.

Nexium can be taken with food or on an empty stomach.

If you forget to take it

If you forget to take a dose, take it as soon as you remember, and then go back to taking it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

Taking too much (overdose)

Telephone your doctor or the Poisons Information Centre (13 11 26) or go to Accident and Emergency at your nearest hospital immediately if you think that you or anyone else may have taken too many Nexium. Do this even if there are no signs of discomfort or poisoning.

While you are taking NEXIUM

Things you must do

Take Nexium exactly as your doctor has prescribed.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking Nexium.

Tell all doctors, dentists and pharmacists who are treating you that you are taking Nexium.

Tell your doctor if you become pregnant while you are taking Nexium.

Tell your doctor if your symptoms return.

Although Nexium can heal ulcers successfully, it may not prevent them recurring at a later date.

If you need to have any medical tests while you are taking Nexium, tell your doctor.

It may affect the results of some tests.

Things you must not do

Do not take it to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Nexium.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- nausea or vomiting
- constipation
- diarrhoea
- headache
- wind
- stomach pain
- skin rash, itchy skin
- dizziness

- dry mouth.

These side effects are usually mild.

Tell your doctor immediately if you notice any of the following:

- blurred vision
- mood changes, confusion or depression
- muscle pain or weakness, joint pain
- increase in breast size (males)
- increased sweating
- changes in sleep patterns
- fever
- increased bruising
- "pins and needles"
- hair loss
- tremor
- blood in the urine

These side effects may require medical attention.

If you notice any of the following happen, tell your doctor immediately or go to Accident and Emergency at the nearest hospital:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- severe skin reaction which may include rash, itching, redness, blistering or peeling of the skin
- signs of liver inflammation including yellowing of the skin or eyes, feeling generally unwell, nausea, vomiting, loss of appetite.

These are very serious side effects. You may need urgent medical treatment or hospitalisation.

Occasionally, Nexium may be associated with changes in your liver or blood, which may require your doctor to do certain blood tests.

Tell your doctor if you think you have any of these effects or notice anything else that is making you feel unwell.

Some people may get other side effects while taking Nexium.

Other problems are more likely to arise from the condition itself rather than the treatment.

For this reason, contact your doctor immediately if you notice any of the following:

- pain or indigestion during treatment with Nexium
- you begin to vomit blood or food
- you pass black (blood-stained) motions.

After taking it

Storage

Keep your Nexium in the blister pack until it is time to take them.

If you take Nexium out of the blister pack it will not keep well.

Keep it in a cool, dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on a window sill.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking Nexium or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets you have left over.

Product description

What Nexium looks like

Tablets

Nexium 20 mg are light pink, oblong shaped tablets engraved 20 mg on one side and A / EH on the other.

Nexium 40 mg are pink, oblong shaped tablets engraved 40 mg on one side and A / EI on the other.

Nexium Granules for oral suspension

Nexium 10 mg granules for oral suspension are pale yellow fine granules (brownish granules may be visible) in a unit dose sachet.

Ingredients

Tablets

Each Nexium tablet contains esomeprazole magnesium trihydrate as the active ingredient equivalent to esomeprazole 20mg or 40mg;

Plus the following inactive ingredients,

- Glyceryl monostearate (E 471)
- Hydroxypropyl cellulose
- Hypromellose
- Magnesium stearate (E 572)
- Methacrylic acid copolymer
- Microcrystalline cellulose (E 460).
- Paraffin hard
- Macrogol 6000
- Polysorbate 80 (E 433)
- Crospovidone
- Sodium stearyl fumarate
- Purified talc (E 553(b))
- Titanium dioxide (E 171)
- Triethyl citrate
- Sugar spheres (maize starch and sucrose).

The tablets are coloured with iron oxide red CI77491 and/or iron oxide yellow CI77492

Nexium Granules for oral suspension

Each sachet of Nexium granules for oral suspension contains esomeprazole magnesium trihydrate as the active ingredient equivalent to esomeprazole 10mg; plus,

- glyceryl monostearate

- hydroxypropylcellulose
- hypromellose
- magnesium stearate
- methacrylic acid copolymer
- polysorbate 80
- talc
- triethyl citrate
- glucose - anhydrous
- xanthan gum
- crospovidone
- citric acid - anhydrous
- iron oxide yellow
- sugar spheres (maize starch and sucrose).

Nexium tablets and granules for oral suspension do not contain gluten.

Nexium tablets are available in blister packs of 7 or 30 tablets.

Nexium granules are available in packs containing 30 unit dose sachets.

Sponsor

AstraZeneca Pty Ltd

ABN 54 009 682 311

Alma Road

NORTH RYDE NSW 2113

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Australian Registration Number

Nexium 20 mg (blister) - 74133

Nexium 40 mg (blister) - 74134

Nexium 10 mg (sachet) - 135726

Non-marketed presentations

Nexium 20 mg (bottle) - 75726

Nexium 40 mg (bottle) - 75727

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NEXIUM®

Esomeprazole magnesium trihydrate

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If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What NEXIUM is used for

Reflux Oesophagitis

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Reflux can cause a burning sensation in the chest rising up to the throat, also known as heartburn.

NEXIUM is also taken to help stop reflux oesophagitis coming back or relapsing.

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Most people who have a peptic (gastric and duodenal) ulcer also have a bacterium called *Helicobacter pylori* in their stomach.

Depending on the position of the ulcer it is called a gastric or duodenal ulcer. A gastric ulcer occurs in the stomach. A duodenal ulcer occurs in the duodenum which is the tube leading out from the stomach.

If you have a peptic ulcer, your doctor will prescribe NEXIUM with antibiotics. When NEXIUM and antibiotics are taken together, they work to kill the bacterium and let your ulcer heal. You may need further treatment with antibiotics.

Zollinger-Ellison Syndrome

NEXIUM is also used to treat a rare condition called Zollinger-Ellison syndrome, where the stomach produces large amounts of acid, much more than in ulcers or reflux disease.

Bleeding Peptic Ulcers

When peptic ulcers become severe enough, they start to bleed. You may receive treatment injected into your veins initially. This treatment may be followed with NEXIUM tablets or granules prescribed by your doctor for a longer period of time. This is to help your ulcer/s to heal.

How NEXIUM works

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Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

Ask your doctor if you want more information.

Your doctor may have prescribed NEXIUM for another reason.

There is no evidence that NEXIUM is addictive.

Before you take NEXIUM

When you must not take it

Do not take NEXIUM if you have allergies to:

- esomeprazole or any ingredient listed at the end of this leaflet
- any medicines containing a proton-pump inhibitor

How to take NEXIUM

Follow all directions given to you by your doctor and pharmacist carefully.

These instructions may differ from the information contained in this leaflet

If you do not understand the directions on the label, ask your doctor or pharmacist for help.

How to take it

NEXIUM is available as tablets and as granules for suspension in sachets.

NEXIUM Tablets

Take one NEXIUM tablet each day, unless your doctor has told you otherwise.

The dose of NEXIUM tablets is usually 20 mg or 40 mg a day depending on what condition you are being treated for and how severe it is.

Swallow NEXIUM tablets whole with a glass of water. Do not crush or chew the tablets.

If the tablets are chewed or crushed they will not work properly.

If you have difficulty swallowing the tablets:

1. Place the tablet in half a glass of non-carbonated water. Mineral water or other liquids are not suitable.
2. Gently mix the tablet and water by stirring, taking care not to crush the tablet.
3. Stir until the tablet dissolves into little pellets.
4. Drink the liquid with the pellets immediately, or within 30 minutes. Do not chew the pellets.
5. Rinse the glass with half a glass of water and drink.

If you cannot swallow at all, follow steps 1-3 above to disperse the tablets and administer the liquid and pellets through a gastric tube.

NEXIUM Sachets

NEXIUM sachets are usually used for children or adults who have

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take NEXIUM if you are also taking atazanavir or cilostazol.

Please check with your doctor or pharmacist if you are taking these medicines. These medicines will be affected by NEXIUM.

NEXIUM is not approved for use in children younger than 1 year of age.

There is no specific information about use in children younger than 1 year of age, so NEXIUM is not recommended in these patients.

Do not take NEXIUM after the use by (expiry) date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to take it

You must tell your doctor if you have:

- allergies to any other medicines, foods, dyes or preservatives
- any problems with your liver
- severe kidney problems
- any other medical conditions

Do not take NEXIUM if you are pregnant or breastfeeding unless your doctor says so. Ask your doctor about the risks and benefits involved.

It is not known if it is safe for you to take NEXIUM while you are pregnant. It may affect your baby.

It is not known if your baby can take in NEXIUM from breast milk if you are breastfeeding.

Taking other medicines

Do not take NEXIUM if you are taking the following medicines:

- atazanavir and nelfinavir - medicines used to treat viral infections such as HIV

- cilostazol - a medicine used to treat intermittent claudication

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with NEXIUM. These include:

- ketoconazole, itraconazole and voriconazole - medicines used to treat fungal infections
- diazepam - a medicine used to treat anxiety and some other conditions
- phenytoin - a medicine used to treat epilepsy or fits
- citalopram, clomipramine and imipramine - medicines used to treat depression
- St John's wort - a herbal remedy used to treat mood disorders
- clarithromycin and rifampicin - medicines used to treat bacterial infections
- warfarin and clopidogrel - medicines used to prevent blood clots
- digoxin - a medicine used to treat heart conditions
- methotrexate - a medicine used to treat arthritis and some types of cancer
- tacrolimus - a medicine used to assist in organ transplants
- erlotinib or related medicines used to treat cancer

These medicines may be affected by NEXIUM or may affect how well it works. You may need different amounts of your medicine or you may need to take different medicines. Your doctor can tell you what to do if you are taking any other medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking NEXIUM.

If you have not told your doctor about any of these things, tell them before you take NEXIUM.

trouble swallowing tablets. The dose of NEXIUM sachets is 10 to 20 mg a day depending on what condition is being treated and how severe it is.

The granules in NEXIUM sachets should be dispersed as follows in non-carbonated water (mineral water is not suitable) before being taken:

1. For a 10 mg dose empty the contents of a 10 mg sachet into a glass containing 15 mL of water. For a 20 mg dose empty the contents of two 10 mg sachets into a glass containing 30 mL of water.
2. Stir the contents and leave for a few minutes to thicken.
3. Stir again and drink within 30 minutes.
4. If any material remains after drinking, add more water, stir and drink immediately.

For patients who cannot swallow, NEXIUM granules for oral suspension can be administered via a large syringe through a nasogastric or gastric tube:

1. For a 10 mg dose add the contents of a 10 mg sachet to a syringe containing 15 mL of water. For a 20 mg dose add the contents of two 10 mg sachets to a syringe containing 30 mL of water.
2. Immediately shake the syringe and leave for a few minutes to thicken.
3. Shake the syringe and inject through the nasogastric or gastric tube within 30 minutes.
4. Refill the syringe with 15 mL of water, then shake and flush any remaining contents from the nasogastric or gastric tube into the stomach.

Do not crush or chew the pellets in the suspension.

If the pellets are chewed or crushed they will not work properly.

Take NEXIUM at about the same time each day.

Keeping a regular time for taking NEXIUM will help to remind you to take it.

Keep taking NEXIUM for as long as your doctor recommends.

In most patients, NEXIUM relieves symptoms rapidly and healing is usually complete within 4 weeks. Continue taking NEXIUM for as long as your doctor tells you to.

NEXIUM can be taken with food or on an empty stomach.

If you forget to take it

If you forget to take a dose, take it as soon as you remember, and then go back to taking it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

Taking too much (overdose)

Telephone your doctor or the Poisons Information Centre (13 11 26) or go to Accident and Emergency at your nearest hospital immediately if you think that you or anyone else may have taken too many NEXIUM. Do this even if there are no signs of discomfort or poisoning.

While you are taking NEXIUM

Things you must do

Take NEXIUM exactly as your doctor has prescribed.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking NEXIUM.

Tell all doctors, dentists and pharmacists who are treating you that you are taking NEXIUM.

Tell your doctor if you become pregnant while you are taking NEXIUM.

Tell your doctor if your symptoms return.

Although NEXIUM can heal ulcers successfully, it may not prevent them recurring at a later date.

If you need to have any medical tests while you are taking NEXIUM, tell your doctor.

It may affect the results of some tests.

Things you must not do

Do not take it to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking NEXIUM.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- nausea or vomiting
- constipation
- diarrhoea
- headache
- wind
- stomach pain
- skin rash, itchy skin

- dizziness
- dry mouth

These side effects are usually mild.

Tell your doctor immediately if you notice any of the following:

- blurred vision
- mood changes, confusion or depression
- muscle pain or weakness, joint pain
- increase in breast size (males)
- increased sweating
- changes in sleep patterns
- fever
- increased bruising
- "pins and needles"
- hair loss
- tremor
- blood in the urine

These side effects may require medical attention.

If you notice any of the following happen, tell your doctor immediately or go to Accident and Emergency at the nearest hospital:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- severe skin reaction which may include rash, itching, redness, blistering or peeling of the skin
- signs of liver inflammation including yellowing of the skin or eyes, feeling generally unwell, nausea, vomiting, loss of appetite

These are very serious side effects. You may need urgent medical treatment or hospitalisation.

Occasionally, NEXIUM may be associated with changes in your liver or blood, which may require your doctor to do certain blood tests.

Tell your doctor if you think you have any of these effects or notice anything else that is making you feel unwell.

Some people may get other side effects while taking NEXIUM.

Other problems are more likely to arise from the condition itself rather than the treatment.

For this reason, contact your doctor immediately if you notice any of the following:

- pain or indigestion during treatment with NEXIUM
- you begin to vomit blood or food
- you pass black (blood-stained) motions

After taking it

Storage

Keep your NEXIUM in the blister pack until it is time to take them.

If you take NEXIUM out of the blister pack it will not keep well.

Keep it in a cool, dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on a window sill.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking NEXIUM or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets you have left over.

Product description

What NEXIUM looks like

Tablets

NEXIUM 20 mg are light pink, oblong shaped tablets engraved 20

mg on one side and A / EH on the other.

NEXIUM 40 mg are pink, oblong shaped tablets engraved 40 mg on one side and A / EI on the other.

NEXIUM Granules for oral suspension

NEXIUM 10 mg granules for oral suspension are pale yellow fine granules (brownish granules may be visible) in a unit dose sachet.

Ingredients

Tablets

Each NEXIUM tablet contains esomeprazole magnesium trihydrate as the active ingredient equivalent to esomeprazole 20 mg or 40 mg.

Plus the following inactive ingredients:

- Glyceryl monostearate (E 471)
- Hydroxypropyl cellulose
- Hypromellose
- Magnesium stearate (E 572)
- Methacrylic acid copolymer
- Microcrystalline cellulose (E 460)
- Paraffin hard
- Macrogol 6000
- Polysorbate 80 (E 433)
- Crospovidone
- Sodium stearyl fumarate
- Purified talc (E 553(b))
- Titanium dioxide (E 171)
- Triethyl citrate
- Sugar spheres (maize starch and sucrose)

The tablets are coloured with iron oxide red CI77491 and/or iron oxide yellow CI77492.

NEXIUM Granules for oral suspension

Each sachet of NEXIUM granules for oral suspension contains esomeprazole magnesium trihydrate as the active ingredient equivalent to esomeprazole 10 mg.

Plus the following inactive ingredients:

- glyceryl monostearate

- hydroxypropylcellulose
- hypromellose
- magnesium stearate
- methacrylic acid copolymer
- polysorbate 80
- talc
- triethyl citrate
- glucose - anhydrous
- xanthan gum
- crospovidone
- citric acid - anhydrous
- iron oxide yellow
- sugar spheres (maize starch and sucrose)

NEXIUM tablets and granules for oral suspension do not contain gluten.

NEXIUM tablets are available in blister packs of 7 or 30 tablets.

NEXIUM granules are available in packs containing 30 unit dose sachets.

Sponsor

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ABN 54 009 682 311

Alma Road

NORTH RYDE NSW 2113

Australian Registration Numbers:

NEXIUM 20 mg (blister) - 74133

NEXIUM 40 mg (blister) - 74134

NEXIUM 10 mg (sachet) - 135726

Non-marketed presentations

NEXIUM 20 mg (bottle) - 75726

NEXIUM 40 mg (bottle) - 75727

This leaflet was prepared in June 2014.

NEXIUM® is a registered trade mark of the AstraZeneca group of companies.

NEXIUM®

Esomeprazole magnesium trihydrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions people ask about NEXIUM. It does not contain all the information that is known about NEXIUM.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking NEXIUM against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What NEXIUM is used for

Reflux Oesophagitis

NEXIUM is taken to treat reflux oesophagitis. This can be caused by "washing back" (reflux) of food and acid from the stomach into the food pipe (oesophagus).

Reflux can cause a burning sensation in the chest rising up to the throat, also known as heartburn.

NEXIUM is also taken to help stop reflux oesophagitis coming back or relapsing.

Upper gastrointestinal symptoms associated with non-steroidal anti-inflammatory drugs (NSAIDs) therapy

NEXIUM is taken to treat the symptoms of pain or discomfort, in the stomach caused by NSAIDs, a type of medicine for pain or inflammation.

NEXIUM is also taken to help heal and prevent ulcers caused by NSAIDs.

Peptic Ulcers Associated with *Helicobacter pylori* Infection

Most people who have a peptic (gastric and duodenal) ulcer also have a bacterium called *Helicobacter pylori* in their stomach.

Depending on the position of the ulcer it is called a gastric or duodenal ulcer. A gastric ulcer occurs in the stomach. A duodenal ulcer occurs in the duodenum which is the tube leading out from the stomach.

If you have a peptic ulcer, your doctor will prescribe NEXIUM with antibiotics. When NEXIUM and antibiotics are taken together, they work to kill the bacterium and let your ulcer heal. You may need further treatment with antibiotics.

Zollinger-Ellison Syndrome

NEXIUM is also used to treat a rare condition called Zollinger-Ellison syndrome, where the stomach produces large amounts of acid, much more than in ulcers or reflux disease.

Bleeding Peptic Ulcers

When peptic ulcers become severe enough, they start to bleed. You may receive treatment injected into your veins initially. This treatment may be followed with NEXIUM tablets or granules prescribed by your doctor for a longer period of time. This is to help your ulcer/s to heal.

How NEXIUM works

NEXIUM is a type of medicine called a proton-pump inhibitor. It works by decreasing the amount of acid made by the stomach, to give relief of symptoms and allow healing to take place. This does not stop food being digested in the normal way.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

Ask your doctor if you want more information.

Your doctor may have prescribed NEXIUM for another reason.

There is no evidence that NEXIUM is addictive.

Before you take NEXIUM

When you must not take it

Do not take NEXIUM if you have allergies to:

- esomeprazole or any ingredient listed at the end of this leaflet
- any medicines containing a proton-pump inhibitor

How to take NEXIUM

Follow all directions given to you by your doctor and pharmacist carefully.

These instructions may differ from the information contained in this leaflet

If you do not understand the directions on the label, ask your doctor or pharmacist for help.

How to take it

NEXIUM is available as tablets and as granules for suspension in sachets.

NEXIUM Tablets

Take one NEXIUM tablet each day, unless your doctor has told you otherwise.

The dose of NEXIUM tablets is usually 20 mg or 40 mg a day depending on what condition you are being treated for and how severe it is.

Swallow NEXIUM tablets whole with a glass of water. Do not crush or chew the tablets.

If the tablets are chewed or crushed they will not work properly.

If you have difficulty swallowing the tablets:

1. Place the tablet in half a glass of non-carbonated water. Mineral water or other liquids are not suitable.
2. Gently mix the tablet and water by stirring, taking care not to crush the tablet.
3. Stir until the tablet dissolves into little pellets.
4. Drink the liquid with the pellets immediately, or within 30 minutes. Do not chew the pellets.
5. Rinse the glass with half a glass of water and drink.

If you cannot swallow at all, follow steps 1-3 above to disperse the tablets and administer the liquid and pellets through a gastric tube.

NEXIUM Sachets

NEXIUM sachets are usually used for children or adults who have

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take NEXIUM if you are also taking atazanavir or cilostazol.

Please check with your doctor or pharmacist if you are taking these medicines. These medicines will be affected by NEXIUM.

NEXIUM is not approved for use in children younger than 1 year of age.

There is no specific information about use in children younger than 1 year of age, so NEXIUM is not recommended in these patients.

Do not take NEXIUM after the use by (expiry) date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to take it

You must tell your doctor if you have:

- allergies to any other medicines, foods, dyes or preservatives
- any problems with your liver
- severe kidney problems
- any other medical conditions

Do not take NEXIUM if you are pregnant or breastfeeding unless your doctor says so. Ask your doctor about the risks and benefits involved.

It is not known if it is safe for you to take NEXIUM while you are pregnant. It may affect your baby.

It is not known if your baby can take in NEXIUM from breast milk if you are breastfeeding.

Taking other medicines

Do not take NEXIUM if you are taking the following medicines:

- atazanavir and nelfinavir - medicines used to treat viral infections such as HIV

- cilostazol - a medicine used to treat intermittent claudication

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with NEXIUM. These include:

- ketoconazole, itraconazole and voriconazole - medicines used to treat fungal infections
- diazepam - a medicine used to treat anxiety and some other conditions
- phenytoin - a medicine used to treat epilepsy or fits
- citalopram, clomipramine and imipramine - medicines used to treat depression
- St John's wort - a herbal remedy used to treat mood disorders
- clarithromycin and rifampicin - medicines used to treat bacterial infections
- warfarin and clopidogrel - medicines used to prevent blood clots
- digoxin - a medicine used to treat heart conditions
- methotrexate - a medicine used to treat arthritis and some types of cancer
- tacrolimus - a medicine used to assist in organ transplants
- erlotinib or related medicines used to treat cancer

These medicines may be affected by NEXIUM or may affect how well it works. You may need different amounts of your medicine or you may need to take different medicines. Your doctor can tell you what to do if you are taking any other medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking NEXIUM.

If you have not told your doctor about any of these things, tell them before you take NEXIUM.

trouble swallowing tablets. The dose of NEXIUM sachets is 10 to 20 mg a day depending on what condition is being treated and how severe it is.

The granules in NEXIUM sachets should be dispersed as follows in non-carbonated water (mineral water is not suitable) before being taken:

1. For a 10 mg dose empty the contents of a 10 mg sachet into a glass containing 15 mL of water. For a 20 mg dose empty the contents of two 10 mg sachets into a glass containing 30 mL of water.
2. Stir the contents and leave for a few minutes to thicken.
3. Stir again and drink within 30 minutes.
4. If any material remains after drinking, add more water, stir and drink immediately.

For patients who cannot swallow, NEXIUM granules for oral suspension can be administered via a large syringe through a nasogastric or gastric tube:

1. For a 10 mg dose add the contents of a 10 mg sachet to a syringe containing 15 mL of water. For a 20 mg dose add the contents of two 10 mg sachets to a syringe containing 30 mL of water.
2. Immediately shake the syringe and leave for a few minutes to thicken.
3. Shake the syringe and inject through the nasogastric or gastric tube within 30 minutes.
4. Refill the syringe with 15 mL of water, then shake and flush any remaining contents from the nasogastric or gastric tube into the stomach.

Do not crush or chew the pellets in the suspension.

If the pellets are chewed or crushed they will not work properly.

Take NEXIUM at about the same time each day.

Keeping a regular time for taking NEXIUM will help to remind you to take it.

Keep taking NEXIUM for as long as your doctor recommends.

In most patients, NEXIUM relieves symptoms rapidly and healing is usually complete within 4 weeks. Continue taking NEXIUM for as long as your doctor tells you to.

NEXIUM can be taken with food or on an empty stomach.

If you forget to take it

If you forget to take a dose, take it as soon as you remember, and then go back to taking it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

Taking too much (overdose)

Telephone your doctor or the Poisons Information Centre (13 11 26) or go to Accident and Emergency at your nearest hospital immediately if you think that you or anyone else may have taken too many NEXIUM. Do this even if there are no signs of discomfort or poisoning.

While you are taking NEXIUM

Things you must do

Take NEXIUM exactly as your doctor has prescribed.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking NEXIUM.

Tell all doctors, dentists and pharmacists who are treating you that you are taking NEXIUM.

Tell your doctor if you become pregnant while you are taking NEXIUM.

Tell your doctor if your symptoms return.

Although NEXIUM can heal ulcers successfully, it may not prevent them recurring at a later date.

If you need to have any medical tests while you are taking NEXIUM, tell your doctor.

It may affect the results of some tests.

Things you must not do

Do not take it to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking NEXIUM.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- nausea or vomiting
- constipation
- diarrhoea
- headache
- wind
- stomach pain
- skin rash, itchy skin

- dizziness
- dry mouth

These side effects are usually mild.

Tell your doctor immediately if you notice any of the following:

- blurred vision
- mood changes, confusion or depression
- muscle pain or weakness, joint pain
- increase in breast size (males)
- increased sweating
- changes in sleep patterns
- fever
- increased bruising
- "pins and needles"
- hair loss
- tremor
- blood in the urine

These side effects may require medical attention.

If you notice any of the following happen, tell your doctor immediately or go to Accident and Emergency at the nearest hospital:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- severe skin reaction which may include rash, itching, redness, blistering or peeling of the skin
- signs of liver inflammation including yellowing of the skin or eyes, feeling generally unwell, nausea, vomiting, loss of appetite

These are very serious side effects. You may need urgent medical treatment or hospitalisation.

Occasionally, NEXIUM may be associated with changes in your liver or blood, which may require your doctor to do certain blood tests.

Tell your doctor if you think you have any of these effects or notice anything else that is making you feel unwell.

Some people may get other side effects while taking NEXIUM.

Other problems are more likely to arise from the condition itself rather than the treatment.

For this reason, contact your doctor immediately if you notice any of the following:

- pain or indigestion during treatment with NEXIUM
- you begin to vomit blood or food
- you pass black (blood-stained) motions

After taking it

Storage

Keep your NEXIUM in the blister pack until it is time to take them.

If you take NEXIUM out of the blister pack it will not keep well.

Keep it in a cool, dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on a window sill.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking NEXIUM or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets you have left over.

Product description

What NEXIUM looks like

Tablets

NEXIUM 20 mg are light pink, oblong shaped tablets engraved 20

mg on one side and A / EH on the other.

NEXIUM 40 mg are pink, oblong shaped tablets engraved 40 mg on one side and A / EI on the other.

NEXIUM Granules for oral suspension

NEXIUM 10 mg granules for oral suspension are pale yellow fine granules (brownish granules may be visible) in a unit dose sachet.

Ingredients

Tablets

Each NEXIUM tablet contains esomeprazole magnesium trihydrate as the active ingredient equivalent to esomeprazole 20 mg or 40 mg.

Plus the following inactive ingredients:

- glyceryl monostearate (E 471)
- hydroxypropyl cellulose
- hypromellose
- magnesium stearate (E 572)
- methacrylic acid copolymer
- microcrystalline cellulose (E 460)
- paraffin synthetic
- macrogol 6000
- polysorbate 80 (E 433)
- crospovidone
- sodium stearyl fumarate
- purified talc (E 553(b))
- titanium dioxide (E 171)
- triethyl citrate
- sugar spheres (maize starch and sucrose)

The tablets are coloured with iron oxide red CI77491 and/or iron oxide yellow CI77492.

NEXIUM Granules for oral suspension

Each sachet of NEXIUM granules for oral suspension contains esomeprazole magnesium trihydrate as the active ingredient equivalent to esomeprazole 10 mg.

Plus the following inactive ingredients:

- glyceryl monostearate

- hydroxypropylcellulose
- hypromellose
- magnesium stearate
- methacrylic acid copolymer
- polysorbate 80
- talc
- triethyl citrate
- glucose - anhydrous
- xanthan gum
- crospovidone
- citric acid - anhydrous
- iron oxide yellow
- sugar spheres (maize starch and sucrose)

Doc ID-002261449 V4.0

NEXIUM tablets and granules for oral suspension do not contain gluten.

NEXIUM tablets are available in blister packs of 7 or 30 tablets.

NEXIUM granules are available in packs containing 30 unit dose sachets.

Sponsor

AstraZeneca Pty Ltd
ABN 54 009 682 311
Alma Road
NORTH RYDE NSW 2113

Australian Registration Numbers:
NEXIUM 20 mg (blister) - 74133
NEXIUM 40 mg (blister) - 74134
NEXIUM 10 mg (sachet) - 135726

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NEXIUM is taken to treat reflux oesophagitis. This can be caused by "washing back" (reflux) of food and acid from the stomach into the food pipe (oesophagus).

Reflux can cause a burning sensation in the chest rising up to the throat, also known as heartburn.

NEXIUM is also taken to help stop reflux oesophagitis coming back or relapsing.

Upper gastrointestinal symptoms associated with non-steroidal anti-inflammatory drugs (NSAIDs) therapy

NEXIUM is taken to treat the symptoms of pain or discomfort, in the stomach caused by NSAIDs, a type of medicine for pain or inflammation.

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Peptic Ulcers Associated with Helicobacter pylori Infection

Most people who have a peptic (gastric and duodenal) ulcer also have a bacterium called *Helicobacter pylori* in their stomach.

Depending on the position of the ulcer it is called a gastric or duodenal ulcer. A gastric ulcer occurs in the stomach. A duodenal ulcer occurs in the duodenum which is the tube leading out from the stomach.

If you have a peptic ulcer, your doctor will prescribe NEXIUM with antibiotics. When NEXIUM and antibiotics are taken together, they work to kill the bacterium and let your ulcer heal. You may need further treatment with antibiotics.

Zollinger-Ellison Syndrome

NEXIUM is also used to treat a rare condition called Zollinger-Ellison syndrome, where the stomach produces large amounts of acid, much more than in ulcers or reflux disease.

Bleeding Peptic Ulcers

When peptic ulcers become severe enough, they start to bleed. You may receive treatment injected into your veins initially. This treatment may be followed with NEXIUM tablets or granules prescribed by your doctor for a longer period of time. This is to help your ulcer/s to heal.

How NEXIUM works

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Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

Ask your doctor if you want more information.

Your doctor may have prescribed NEXIUM for another reason.

There is no evidence that NEXIUM is addictive.

Before you take NEXIUM

When you must not take it

Do not take NEXIUM if you have allergies to:

- esomeprazole or any ingredient listed at the end of this leaflet
- any medicines containing a proton-pump inhibitor

How to take NEXIUM

Follow all directions given to you by your doctor and pharmacist carefully.

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If you do not understand the directions on the label, ask your doctor or pharmacist for help.

How to take it

NEXIUM is available as tablets and as granules for suspension in sachets.

NEXIUM Tablets

Take one NEXIUM tablet each day, unless your doctor has told you otherwise.

The dose of NEXIUM tablets is usually 20 mg or 40 mg a day depending on what condition you are being treated for and how severe it is.

Swallow NEXIUM tablets whole with a glass of water. Do not crush or chew the tablets.

If the tablets are chewed or crushed they will not work properly.

If you have difficulty swallowing the tablets:

1. Place the tablet in half a glass of non-carbonated water. Mineral water or other liquids are not suitable.
2. Gently mix the tablet and water by stirring, taking care not to crush the tablet.
3. Stir until the tablet dissolves into little pellets.
4. Drink the liquid with the pellets immediately, or within 30 minutes. Do not chew the pellets.
5. Rinse the glass with half a glass of water and drink.

If you cannot swallow at all, follow steps 1-3 above to disperse the tablets and administer the liquid and pellets through a gastric tube.

NEXIUM Sachets

NEXIUM sachets are usually used for children or adults who have

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

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NEXIUM is not approved for use in children younger than 1 year of age.

There is no specific information about use in children younger than 1 year of age, so NEXIUM is not recommended in these patients.

Do not take NEXIUM after the use by (expiry) date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to take it

You must tell your doctor if you have:

- allergies to any other medicines, foods, dyes or preservatives
- any problems with your liver
- severe kidney problems
- any other medical conditions

Do not take NEXIUM if you are pregnant or breastfeeding unless your doctor says so. Ask your doctor about the risks and benefits involved.

It is not known if it is safe for you to take NEXIUM while you are pregnant. It may affect your baby.

It is not known if your baby can take in NEXIUM from breast milk if you are breastfeeding.

Taking other medicines

Do not take NEXIUM if you are taking the following medicines:

- atazanavir and nelfinavir - medicines used to treat viral infections such as HIV

- cilostazol - a medicine used to treat intermittent claudication

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with NEXIUM. These include:

- ketoconazole, itraconazole and voriconazole - medicines used to treat fungal infections
- diazepam - a medicine used to treat anxiety and some other conditions
- phenytoin - a medicine used to treat epilepsy or fits
- citalopram, clomipramine and imipramine - medicines used to treat depression
- St John's wort - a herbal remedy used to treat mood disorders
- clarithromycin and rifampicin - medicines used to treat bacterial infections
- warfarin and clopidogrel - medicines used to prevent blood clots
- digoxin - a medicine used to treat heart conditions
- methotrexate - a medicine used to treat arthritis and some types of cancer
- tacrolimus and mycophenolate mofetil - medicines used to assist in organ transplants
- erlotinib or related medicines used to treat cancer

These medicines may be affected by NEXIUM or may affect how well it works. You may need different amounts of your medicine or you may need to take different medicines. Your doctor can tell you what to do if you are taking any other medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking NEXIUM.

If you have not told your doctor about any of these things, tell them before you take NEXIUM.

trouble swallowing tablets. The dose of NEXIUM sachets is 10 to 20 mg a day depending on what condition is being treated and how severe it is.

The granules in NEXIUM sachets should be dispersed as follows in non-carbonated water (mineral water is not suitable) before being taken:

1. For a 10 mg dose empty the contents of a 10 mg sachet into a glass containing 15 mL of water. For a 20 mg dose empty the contents of two 10 mg sachets into a glass containing 30 mL of water.
2. Stir the contents and leave for a few minutes to thicken.
3. Stir again and drink within 30 minutes.
4. If any material remains after drinking, add more water, stir and drink immediately.

For patients who cannot swallow, NEXIUM granules for oral suspension can be administered via a large syringe through a nasogastric or gastric tube:

1. For a 10 mg dose add the contents of a 10 mg sachet to a syringe containing 15 mL of water. For a 20 mg dose add the contents of two 10 mg sachets to a syringe containing 30 mL of water.
2. Immediately shake the syringe and leave for a few minutes to thicken.
3. Shake the syringe and inject through the nasogastric or gastric tube within 30 minutes.
4. Refill the syringe with 15 mL of water, then shake and flush any remaining contents from the nasogastric or gastric tube into the stomach.

Do not crush or chew the pellets in the suspension.

If the pellets are chewed or crushed they will not work properly.

Take NEXIUM at about the same time each day.

Keeping a regular time for taking NEXIUM will help to remind you to take it.

Keep taking NEXIUM for as long as your doctor recommends.

In most patients, NEXIUM relieves symptoms rapidly and healing is usually complete within 4 weeks. Continue taking NEXIUM for as long as your doctor tells you to.

NEXIUM can be taken with food or on an empty stomach.

If you forget to take it

If you forget to take a dose, take it as soon as you remember, and then go back to taking it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

Taking too much (overdose)

Telephone your doctor or the Poisons Information Centre (13 11 26) or go to Accident and Emergency at your nearest hospital immediately if you think that you or anyone else may have taken too many NEXIUM. Do this even if there are no signs of discomfort or poisoning.

While you are taking NEXIUM

Things you must do

Take NEXIUM exactly as your doctor has prescribed.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking NEXIUM.

Tell all doctors, dentists and pharmacists who are treating you that you are taking NEXIUM.

Tell your doctor if you become pregnant while you are taking NEXIUM.

Tell your doctor if your symptoms return.

Although NEXIUM can heal ulcers successfully, it may not prevent them recurring at a later date.

If you need to have any medical tests while you are taking NEXIUM, tell your doctor.

It may affect the results of some tests.

Things you must not do

Do not take it to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking NEXIUM.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- nausea or vomiting
- constipation
- diarrhoea
- headache
- wind
- stomach pain
- skin rash, itchy skin

- dizziness
- dry mouth

These side effects are usually mild.

Tell your doctor immediately if you notice any of the following:

- blurred vision
- mood changes, confusion or depression
- muscle pain or weakness, joint pain
- increase in breast size (males)
- increased sweating
- changes in sleep patterns
- fever
- increased bruising
- "pins and needles"
- hair loss
- tremor
- blood in the urine

These side effects may require medical attention.

If you notice any of the following happen, tell your doctor immediately or go to Accident and Emergency at the nearest hospital:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- severe skin reaction which may include rash, itching, redness, blistering or peeling of the skin
- signs of liver inflammation including yellowing of the skin or eyes, feeling generally unwell, nausea, vomiting, loss of appetite

These are very serious side effects. You may need urgent medical treatment or hospitalisation.

Occasionally, NEXIUM may be associated with changes in your liver or blood, which may require your doctor to do certain blood tests.

Tell your doctor if you think you have any of these effects or notice anything else that is making you feel unwell.

Some people may get other side effects while taking NEXIUM.

Other problems are more likely to arise from the condition itself rather than the treatment.

For this reason, contact your doctor immediately if you notice any of the following:

- pain or indigestion during treatment with NEXIUM
- you begin to vomit blood or food
- you pass black (blood-stained) motions

After taking it

Storage

Keep your NEXIUM in the blister pack until it is time to take them.

If you take NEXIUM out of the blister pack it will not keep well.

Keep it in a cool, dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on a window sill.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking NEXIUM or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets you have left over.

Product description

What NEXIUM looks like

Tablets

NEXIUM 20 mg are light pink, oblong shaped tablets engraved 20

mg on one side and A / EH on the other.

NEXIUM 40 mg are pink, oblong shaped tablets engraved 40 mg on one side and A / EI on the other.

NEXIUM Granules for oral suspension

NEXIUM 10 mg granules for oral suspension are pale yellow fine granules (brownish granules may be visible) in a unit dose sachet.

Ingredients

Tablets

Each NEXIUM tablet contains esomeprazole magnesium trihydrate as the active ingredient equivalent to esomeprazole 20 mg or 40 mg.

Plus the following inactive ingredients:

- glyceryl monostearate (E 471)
- hydroxypropyl cellulose
- hypromellose
- magnesium stearate (E 572)
- methacrylic acid copolymer
- microcrystalline cellulose (E 460)
- paraffin synthetic
- macrogol 6000
- polysorbate 80 (E 433)
- crospovidone
- sodium stearyl fumarate
- purified talc (E 553(b))
- titanium dioxide (E 171)
- triethyl citrate
- sugar spheres (maize starch and sucrose)

The tablets are coloured with iron oxide red CI77491 and/or iron oxide yellow CI77492.

NEXIUM Granules for oral suspension

Each sachet of NEXIUM granules for oral suspension contains esomeprazole magnesium trihydrate as the active ingredient equivalent to esomeprazole 10 mg.

Plus the following inactive ingredients:

- glyceryl monostearate

- hydroxypropylcellulose
- hypromellose
- magnesium stearate
- methacrylic acid copolymer
- polysorbate 80
- talc
- triethyl citrate
- glucose - anhydrous
- xanthan gum
- crospovidone
- citric acid - anhydrous
- iron oxide yellow
- sugar spheres (maize starch and sucrose)

Doc ID-002261449 V5.0

NEXIUM tablets and granules for oral suspension do not contain gluten.

NEXIUM tablets are available in blister packs of 7 or 30 tablets.

NEXIUM granules are available in packs containing 30 unit dose sachets.

Sponsor

AstraZeneca Pty Ltd

ABN 54 009 682 311

Alma Road

NORTH RYDE NSW 2113

Australian Registration Numbers:

NEXIUM 20 mg (blister) - 74133

NEXIUM 40 mg (blister) - 74134

NEXIUM 10 mg (sachet) - 135726

Non-marketed presentations

NEXIUM 20 mg (bottle) - 75726

NEXIUM 40 mg (bottle) - 75727

This leaflet was prepared in June 2015.

NEXIUM® is a registered trade mark of the AstraZeneca group of companies.

NEXIUM®

Esomeprazole magnesium trihydrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions people ask about NEXIUM. It does not contain all the information that is known about NEXIUM.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking NEXIUM against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What NEXIUM is used for

Reflux Oesophagitis

NEXIUM is taken to treat reflux oesophagitis. This can be caused by "washing back" (reflux) of food and acid from the stomach into the food pipe (oesophagus).

Reflux can cause a burning sensation in the chest rising up to the throat, also known as heartburn.

NEXIUM is also taken to help stop reflux oesophagitis coming back or relapsing.

Upper gastrointestinal symptoms associated with non-steroidal anti-inflammatory drugs (NSAIDs) therapy

NEXIUM is taken to treat the symptoms of pain or discomfort, in the stomach caused by NSAIDs, a type of medicine for pain or inflammation.

NEXIUM is also taken to help heal and prevent ulcers caused by NSAIDs.

Peptic Ulcers Associated with Helicobacter pylori Infection

Most people who have a peptic (gastric and duodenal) ulcer also have a bacterium called *Helicobacter pylori* in their stomach.

Depending on the position of the ulcer it is called a gastric or duodenal ulcer. A gastric ulcer occurs in the stomach. A duodenal ulcer occurs in the duodenum which is the tube leading out from the stomach.

If you have a peptic ulcer, your doctor will prescribe NEXIUM with antibiotics. When NEXIUM and antibiotics are taken together, they work to kill the bacterium and let your ulcer heal. You may need further treatment with antibiotics.

Zollinger-Ellison Syndrome

NEXIUM is also used to treat a rare condition called Zollinger-Ellison syndrome, where the stomach produces large amounts of acid, much more than in ulcers or reflux disease.

Bleeding Peptic Ulcers

When peptic ulcers become severe enough, they start to bleed. You may receive treatment injected into your veins initially. This treatment may be followed with NEXIUM tablets or granules prescribed by your doctor for a longer period of time. This is to help your ulcer/s to heal.

How NEXIUM works

NEXIUM is a type of medicine called a proton-pump inhibitor. It works by decreasing the amount of acid made by the stomach, to give relief of symptoms and allow healing to take place. This does not stop food being digested in the normal way.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

Ask your doctor if you want more information.

Your doctor may have prescribed NEXIUM for another reason.

There is no evidence that NEXIUM is addictive.

Before you take NEXIUM

When you must not take it

Do not take NEXIUM if you have allergies to:

- esomeprazole or any ingredient listed at the end of this leaflet
- any medicines containing a proton-pump inhibitor

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take NEXIUM if you are also taking atazanavir or cilostazol.

Please check with your doctor or pharmacist if you are taking these medicines. These medicines will be affected by NEXIUM.

NEXIUM is not approved for use in children younger than 1 year of age.

There is no specific information about use in children younger than 1 year of age, so NEXIUM is not recommended in these patients.

Do not take NEXIUM after the use by (expiry) date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to take it

You must tell your doctor if you have:

- allergies to any other medicines, foods, dyes or preservatives
- any problems with your liver
- severe kidney problems
- any other medical conditions
- been diagnosed with osteoporosis

Do not take NEXIUM if you are pregnant or breastfeeding unless your doctor says so. Ask your doctor about the risks and benefits involved.

It is not known if it is safe for you to take NEXIUM while you are pregnant. It may affect your baby.

It is not known if your baby can take in NEXIUM from breast milk if you are breastfeeding.

Taking other medicines

Do not take NEXIUM if you are taking the following medicines:

- atazanavir and nelfinavir - medicines used to treat viral infections such as HIV
- cilostazol - a medicine used to treat intermittent claudication

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with NEXIUM. These include:

- ketoconazole, itraconazole and voriconazole - medicines used to treat fungal infections
- diazepam - a medicine used to treat anxiety and some other conditions
- phenytoin - a medicine used to treat epilepsy or fits
- citalopram, clomipramine and imipramine - medicines used to treat depression
- St John's wort - a herbal remedy used to treat mood disorders
- clarithromycin and rifampicin - medicines used to treat bacterial infections
- warfarin and clopidogrel - medicines used to prevent blood clots
- digoxin - a medicine used to treat heart conditions
- methotrexate - a medicine used to treat arthritis and some types of cancer
- tacrolimus and mycophenolate mofetil - medicines used to assist in organ transplants
- erlotinib or related medicines used to treat cancer

These medicines may be affected by NEXIUM or may affect how well it works. You may need different amounts of your medicine or you may need to take different medicines. Your doctor can tell you what to do if you are taking any other medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking NEXIUM.

If you have not told your doctor about any of these things, tell them before you take NEXIUM.

How to take NEXIUM

Follow all directions given to you by your doctor and pharmacist carefully.

These instructions may differ from the information contained in this leaflet

If you do not understand the directions on the label, ask your doctor or pharmacist for help.

How to take it

NEXIUM is available as tablets and as granules for suspension in sachets.

NEXIUM Tablets

Take one NEXIUM tablet each day, unless your doctor has told you otherwise.

The dose of NEXIUM tablets is usually 20 mg or 40 mg a day depending on what condition you are being treated for and how severe it is.

Swallow NEXIUM tablets whole with a glass of water. Do not crush or chew the tablets.

If the tablets are chewed or crushed they will not work properly.

If you have difficulty swallowing the tablets:

1. Place the tablet in half a glass of non-carbonated water. Mineral water or other liquids are not suitable.
2. Gently mix the tablet and water by stirring, taking care not to crush the tablet.
3. Stir until the tablet dissolves into little pellets.
4. Drink the liquid with the pellets immediately, or within 30 minutes. Do not chew the pellets.
5. Rinse the glass with half a glass of water and drink.

If you cannot swallow at all, follow steps 1-3 above to disperse the

tablets and administer the liquid and pellets through a gastric tube.

NEXIUM Sachets

NEXIUM sachets are usually used for children or adults who have trouble swallowing tablets. The dose of NEXIUM sachets is 10 to 20 mg a day depending on what condition is being treated and how severe it is.

The granules in NEXIUM sachets should be dispersed as follows in non-carbonated water (mineral water is not suitable) before being taken:

1. For a 10 mg dose empty the contents of a 10 mg sachet into a glass containing 15 mL of water. For a 20 mg dose empty the contents of two 10 mg sachets into a glass containing 30 mL of water.
2. Stir the contents and leave for a few minutes to thicken.
3. Stir again and drink within 30 minutes.
4. If any material remains after drinking, add more water, stir and drink immediately.

For patients who cannot swallow, NEXIUM granules for oral suspension can be administered via a large syringe through a nasogastric or gastric tube:

1. For a 10 mg dose add the contents of a 10 mg sachet to a syringe containing 15 mL of water. For a 20 mg dose add the contents of two 10 mg sachets to a syringe containing 30 mL of water.
2. Immediately shake the syringe and leave for a few minutes to thicken.
3. Shake the syringe and inject through the nasogastric or gastric tube within 30 minutes.
4. Refill the syringe with 15 mL of water, then shake and flush any remaining contents from the nasogastric or gastric tube into the stomach.

Do not crush or chew the pellets in the suspension.

If the pellets are chewed or crushed they will not work properly.

Take NEXIUM at about the same time each day.

Keeping a regular time for taking NEXIUM will help to remind you to take it.

Keep taking NEXIUM for as long as your doctor recommends.

In most patients, NEXIUM relieves symptoms rapidly and healing is usually complete within 4 weeks. Continue taking NEXIUM for as long as your doctor tells you to.

NEXIUM can be taken with food or on an empty stomach.

If you forget to take it

If you forget to take a dose, take it as soon as you remember, and then go back to taking it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

Taking too much (overdose)

Telephone your doctor or the Poisons Information Centre (13 11 26) or go to Accident and Emergency at your nearest hospital immediately if you think that you or anyone else may have taken too many NEXIUM. Do this even if there are no signs of discomfort or poisoning.

While you are taking NEXIUM

Things you must do

Take NEXIUM exactly as your doctor has prescribed.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking NEXIUM.

Tell all doctors, dentists and pharmacists who are treating you that you are taking NEXIUM.

Tell your doctor if you become pregnant while you are taking NEXIUM.

Tell your doctor if your symptoms return.

Although NEXIUM can heal ulcers successfully, it may not prevent them recurring at a later date.

If you need to have any medical tests while you are taking NEXIUM, tell your doctor.

It may affect the results of some tests.

Things you must not do

Do not take it to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking NEXIUM.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- nausea or vomiting
- constipation
- diarrhoea
- headache

- wind
- stomach pain
- skin rash, itchy skin
- dizziness
- dry mouth

These side effects are usually mild.

Tell your doctor immediately if you notice any of the following:

- blurred vision
- mood changes, confusion or depression
- muscle pain or weakness, joint pain
- increase in breast size (males)
- increased sweating
- changes in sleep patterns
- fever
- increased bruising
- "pins and needles"
- hair loss
- tremor
- blood in the urine

These side effects may require medical attention.

If you notice any of the following happen, tell your doctor immediately or go to Accident and Emergency at the nearest hospital:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- severe skin reaction which may include rash, itching, redness, blistering or peeling of the skin
- signs of liver inflammation including yellowing of the skin or eyes, feeling generally unwell, nausea, vomiting, loss of appetite

These are very serious side effects. You may need urgent medical treatment or hospitalisation.

Occasionally, NEXIUM may be associated with changes in your liver or blood, which may require your doctor to do certain blood tests.

Tell your doctor if you think you have any of these effects or notice

anything else that is making you feel unwell.

Some people may get other side effects while taking NEXIUM.

Other problems are more likely to arise from the condition itself rather than the treatment.

For this reason, contact your doctor immediately if you notice any of the following:

- pain or indigestion during treatment with NEXIUM
- you begin to vomit blood or food
- you pass black (blood-stained) motions

After taking it

Storage

Keep your NEXIUM in the blister pack until it is time to take them.

If you take NEXIUM out of the blister pack it will not keep well.

Keep it in a cool, dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on a window sill.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking NEXIUM or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets you have left over.

Product description

What NEXIUM looks like

Tablets

NEXIUM 20 mg are light pink, oblong shaped tablets engraved 20 mg on one side and A / EH on the other.

NEXIUM 40 mg are pink, oblong shaped tablets engraved 40 mg on one side and A / EI on the other.

NEXIUM Granules for oral suspension

NEXIUM 10 mg granules for oral suspension are pale yellow fine granules (brownish granules may be visible) in a unit dose sachet.

Ingredients

Tablets

Each NEXIUM tablet contains esomeprazole magnesium trihydrate as the active ingredient equivalent to esomeprazole 20 mg or 40 mg.

Plus the following inactive ingredients:

- glyceryl monostearate (E 471)
- hydroxypropyl cellulose
- hypromellose
- magnesium stearate (E 572)
- methacrylic acid copolymer
- microcrystalline cellulose (E 460)
- paraffin synthetic
- macrogol 6000
- polysorbate 80 (E 433)
- crospovidone
- sodium stearyl fumarate
- purified talc (E 553(b))
- titanium dioxide (E 171)
- triethyl citrate
- sugar spheres (maize starch and sucrose)

The tablets are coloured with iron oxide red CI77491 and/or iron oxide yellow CI77492.

NEXIUM Granules for oral suspension

Each sachet of NEXIUM granules for oral suspension contains esomeprazole magnesium trihydrate as the active ingredient equivalent to esomeprazole 10 mg.

Plus the following inactive ingredients:

- glyceryl monostearate
- hydroxypropylcellulose
- hypromellose
- magnesium stearate
- methacrylic acid copolymer
- polysorbate 80
- talc
- triethyl citrate
- glucose - anhydrous
- xanthan gum
- crospovidone
- citric acid - anhydrous
- iron oxide yellow
- sugar spheres (maize starch and sucrose)

NEXIUM tablets and granules for oral suspension do not contain gluten.

NEXIUM tablets are available in blister packs of 7 or 30 tablets.

NEXIUM granules are available in packs containing 30 unit dose sachets.

This leaflet was prepared in July 2015.

NEXIUM® is a registered trade mark of the AstraZeneca group of companies.

Doc ID-002261449 V6.0

Sponsor

AstraZeneca Pty Ltd

ABN 54 009 682 311

Alma Road

NORTH RYDE NSW 2113

Australian Registration Numbers:

NEXIUM 20 mg (blister) - 74133

NEXIUM 40 mg (blister) - 74134

NEXIUM 10 mg (sachet) - 135726

Non-marketed presentations

NEXIUM 20 mg (bottle) - 75726

NEXIUM 40 mg (bottle) - 75727

NEXIUM[®]

Esomeprazole magnesium trihydrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions people ask about NEXIUM. It does not contain all the information that is known about NEXIUM.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking NEXIUM against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What NEXIUM is used for

Reflux Oesophagitis

NEXIUM is taken to treat reflux oesophagitis. This can be caused by "washing back" (reflux) of food and acid from the stomach into the food pipe (oesophagus).

Reflux can cause a burning sensation in the chest rising up to the throat, also known as heartburn.

NEXIUM is also taken to help stop reflux oesophagitis coming back or relapsing.

Upper gastrointestinal symptoms associated with non-steroidal anti-inflammatory drugs (NSAIDs) therapy

NEXIUM is taken to treat the symptoms of pain or discomfort, in the stomach caused by NSAIDs, a type of medicine for pain or inflammation.

NEXIUM is also taken to help heal and prevent ulcers caused by NSAIDs.

Peptic Ulcers Associated with Helicobacter pylori Infection

Most people who have a peptic (gastric and duodenal) ulcer also have a bacterium called *Helicobacter pylori* in their stomach.

Depending on the position of the ulcer it is called a gastric or duodenal ulcer. A gastric ulcer occurs in the stomach. A duodenal ulcer occurs in the duodenum which is the tube leading out from the stomach.

If you have a peptic ulcer, your doctor will prescribe NEXIUM with antibiotics. When NEXIUM and antibiotics are taken together, they work to kill the bacterium and let your ulcer heal. You may need further treatment with antibiotics.

Zollinger-Ellison Syndrome

NEXIUM is also used to treat a rare condition called Zollinger-Ellison syndrome, where the stomach produces large amounts of acid, much more than in ulcers or reflux disease.

Bleeding Peptic Ulcers

When peptic ulcers become severe enough, they start to bleed. You may receive treatment injected into your veins initially. This treatment may be followed with NEXIUM tablets or granules prescribed by your doctor for a longer period of time. This is to help your ulcer/s to heal.

How NEXIUM works

NEXIUM is a type of medicine called a proton-pump inhibitor. It works by decreasing the amount of acid made by the stomach, to give relief of symptoms and allow healing to take place. This does not stop food being digested in the normal way.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

Ask your doctor if you want more information.

Your doctor may have prescribed NEXIUM for another reason.

There is no evidence that NEXIUM is addictive.

Before you take NEXIUM

When you must not take it

Do not take NEXIUM if you have allergies to:

- esomeprazole or any ingredient listed at the end of this leaflet
- any medicines containing a proton-pump inhibitor

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take NEXIUM if you are also taking atazanavir or cilostazol.

Please check with your doctor or pharmacist if you are taking these medicines. These medicines will be affected by NEXIUM.

NEXIUM is not approved for use in children younger than 1 year of age.

There is no specific information about use in children younger than 1 year of age, so NEXIUM is not recommended in these patients.

Do not take NEXIUM after the use by (expiry) date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to take it

You must tell your doctor if you have:

- allergies to any other medicines, foods, dyes or preservatives
- any problems with your liver
- severe kidney problems
- any other medical conditions
- been diagnosed with osteoporosis
- if you have ever had a skin reaction after treatment with a medicine similar to NEXIUM that reduces stomach acid

Do not take NEXIUM if you are pregnant or breastfeeding unless your doctor says so. Ask your doctor about the risks and benefits involved.

It is not known if it is safe for you to take NEXIUM while you are pregnant. It may affect your baby.

It is not known if your baby can take in NEXIUM from breast milk if you are breastfeeding.

Taking other medicines

Do not take NEXIUM if you are taking the following medicines:

- atazanavir and nelfinavir - medicines used to treat viral infections such as HIV
- cilostazol - a medicine used to treat intermittent claudication

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with NEXIUM. These include:

- ketoconazole, itraconazole and voriconazole - medicines used to treat fungal infections
- diazepam - a medicine used to treat anxiety and some other conditions
- phenytoin - a medicine used to treat epilepsy or fits
- citalopram, clomipramine and imipramine - medicines used to treat depression
- St John's wort - a herbal remedy used to treat mood disorders
- clarithromycin and rifampicin - medicines used to treat bacterial infections
- warfarin and clopidogrel - medicines used to prevent blood clots
- digoxin - a medicine used to treat heart conditions
- methotrexate - a medicine used to treat arthritis and some types of cancer
- tacrolimus and mycophenolate mofetil - medicines used to assist in organ transplants
- erlotinib or related medicines used to treat cancer

These medicines may be affected by NEXIUM or may affect how well it works. You may need different amounts of your medicine or you may need to take different medicines. Your doctor can tell you what to do if you are taking any other medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking NEXIUM.

If you have not told your doctor about any of these things, tell them before you take NEXIUM.

How to take NEXIUM

Follow all directions given to you by your doctor and pharmacist carefully.

These instructions may differ from the information contained in this leaflet

If you do not understand the directions on the label, ask your doctor or pharmacist for help.

How to take it

NEXIUM is available as tablets and as granules for suspension in sachets.

NEXIUM Tablets

Take one NEXIUM tablet each day, unless your doctor has told you otherwise.

The dose of NEXIUM tablets is usually 20 mg or 40 mg a day depending on what condition you are being treated for and how severe it is.

Swallow NEXIUM tablets whole with a glass of water. Do not crush or chew the tablets.

If the tablets are chewed or crushed they will not work properly.

If you have difficulty swallowing the tablets:

1. Place the tablet in half a glass of non-carbonated water. Mineral water or other liquids are not suitable.
2. Gently mix the tablet and water by stirring, taking care not to crush the tablet.
3. Stir until the tablet dissolves into little pellets.
4. Drink the liquid with the pellets immediately, or within 30 minutes. Do not chew the pellets.

5. Rinse the glass with half a glass of water and drink.

If you cannot swallow at all, follow steps 1-3 above to disperse the tablets and administer the liquid and pellets through a gastric tube.

NEXIUM Sachets

NEXIUM sachets are usually used for children or adults who have trouble swallowing tablets. The dose of NEXIUM sachets is 10 to 20 mg a day depending on what condition is being treated and how severe it is.

The granules in NEXIUM sachets should be dispersed as follows in non-carbonated water (mineral water is not suitable) before being taken:

1. For a 10 mg dose empty the contents of a 10 mg sachet into a glass containing 15 mL of water. For a 20 mg dose empty the contents of two 10 mg sachets into a glass containing 30 mL of water.
2. Stir the contents and leave for a few minutes to thicken.
3. Stir again and drink within 30 minutes.
4. If any material remains after drinking, add more water, stir and drink immediately.

For patients who cannot swallow, NEXIUM granules for oral suspension can be administered via a large syringe through a nasogastric or gastric tube:

1. For a 10 mg dose add the contents of a 10 mg sachet to a syringe containing 15 mL of water. For a 20 mg dose add the contents of two 10 mg sachets to a syringe containing 30 mL of water.
2. Immediately shake the syringe and leave for a few minutes to thicken.
3. Shake the syringe and inject through the nasogastric or gastric tube within 30 minutes.
4. Refill the syringe with 15 mL of water, then shake and flush any remaining contents from the

nasogastric or gastric tube into the stomach.

Do not crush or chew the pellets in the suspension.

If the pellets are chewed or crushed they will not work properly.

Take NEXIUM at about the same time each day.

Keeping a regular time for taking NEXIUM will help to remind you to take it.

Keep taking NEXIUM for as long as your doctor recommends.

In most patients, NEXIUM relieves symptoms rapidly and healing is usually complete within 4 weeks. Continue taking NEXIUM for as long as your doctor tells you to.

NEXIUM can be taken with food or on an empty stomach.

If you forget to take it

If you forget to take a dose, take it as soon as you remember, and then go back to taking it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

Taking too much (overdose)

Telephone your doctor or the Poisons Information Centre (13 11 26) or go to Accident and Emergency at your nearest hospital immediately if you think that you or anyone else may have taken too much NEXIUM. Do this even if there are no signs of discomfort or poisoning.

While you are taking NEXIUM

Things you must do

Take NEXIUM exactly as your doctor has prescribed.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking NEXIUM.

Tell all doctors, dentists and pharmacists who are treating you that you are taking NEXIUM.

Tell your doctor if you become pregnant while you are taking NEXIUM.

Tell your doctor if your symptoms return.

Although NEXIUM can heal ulcers successfully, it may not prevent them recurring at a later date.

If you need to have any medical tests while you are taking NEXIUM, tell your doctor.

It may affect the results of some tests.

Things you must not do

Do not take it to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking NEXIUM.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- nausea or vomiting
- constipation
- diarrhoea
- headache
- wind
- stomach pain
- skin rash, itchy skin
- dizziness
- dry mouth

These side effects are usually mild.

Tell your doctor immediately if you notice any of the following:

- blurred vision
- mood changes, confusion or depression
- muscle pain or weakness, joint pain
- increase in breast size (males)
- increased sweating
- changes in sleep patterns
- fever
- increased bruising
- "pins and needles"
- hair loss
- tremor
- blood in the urine
- skin reaction, especially in sun-exposed areas, with joint pain

These side effects may require medical attention.

If you notice any of the following happen, tell your doctor immediately or go to Accident and Emergency at the nearest hospital:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- severe skin reaction which may include rash, itching, redness, blistering or peeling of the skin
- signs of liver inflammation including yellowing of the skin or eyes, feeling generally unwell, nausea, vomiting, loss of appetite

These are very serious side effects. You may need urgent medical treatment or hospitalisation.

Occasionally, NEXIUM may be associated with changes in your liver or blood, which may require your doctor to do certain blood tests.

Tell your doctor if you think you have any of these effects or notice anything else that is making you feel unwell.

Some people may get other side effects while taking NEXIUM.

Other problems are more likely to arise from the condition itself rather than the treatment.

For this reason, contact your doctor immediately if you notice any of the following:

- pain or indigestion during treatment with NEXIUM
- you begin to vomit blood or food
- you pass black (blood-stained) motions

After taking it

Storage

Keep your NEXIUM in the blister pack or sachet until it is time to take it.

If you take NEXIUM out of the blister pack or sachet it will not keep well.

Keep it in a cool, dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on a window sill.

Heat and dampness can destroy some medicines.

Keep NEXIUM where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking NEXIUM or it has passed the expiry date, ask your pharmacist what to do with any left over.

Product description

What NEXIUM looks like

Tablets

NEXIUM 20 mg are light pink, oblong shaped tablets engraved 20 mg on one side and A / EH on the other.

NEXIUM 40 mg are pink, oblong shaped tablets engraved 40 mg on one side and A / EI on the other.

NEXIUM Granules for oral suspension

NEXIUM 10 mg granules for oral suspension are pale yellow fine granules (brownish granules may be visible) in a unit dose sachet.

Ingredients

NEXIUM Tablets

Each NEXIUM tablet contains esomeprazole magnesium trihydrate as the active ingredient equivalent to esomeprazole 20 mg or 40 mg.

Plus, the following inactive ingredients:

- glyceryl monostearate
- hypolose
- hypromellose
- magnesium stearate
- methacrylic acid copolymer
- microcrystalline cellulose
- synthetic paraffin
- macrogol 6000
- polysorbate 80
- crospovidone
- sodium stearyl fumarate
- purified talc
- titanium dioxide
- triethyl citrate

- sugar spheres (maize starch and sucrose)

The tablets are coloured with iron oxide red CI77491 and/or iron oxide yellow CI77492.

NEXIUM Granules for oral suspension

Each sachet of NEXIUM granules for oral suspension contains esomeprazole magnesium trihydrate as the active ingredient equivalent to esomeprazole 10 mg.

Plus, the following inactive ingredients:

- glyceryl monostearate
- hyprolose
- hypromellose
- magnesium stearate
- methacrylic acid copolymer
- polysorbate 80
- talc
- triethyl citrate
- glucose
- xanthan gum
- crospovidone
- citric acid
- iron oxide yellow
- sugar spheres (maize starch and sucrose)

NEXIUM tablets and granules for oral suspension do not contain gluten.

NEXIUM tablets are available in blister packs of 7 or 30 tablets.

NEXIUM granules are available in packs containing 30 unit dose sachets.

Australian Registration Numbers:

NEXIUM 20 mg (blister) - 74133

NEXIUM 40 mg (blister) - 74134

NEXIUM 10 mg (sachet) - 135726

Non-marketed presentations

NEXIUM 20 mg (bottle) - 75726

NEXIUM 40 mg (bottle) - 75727

This leaflet was prepared in April 2019.

NEXIUM® is a registered trade mark of the AstraZeneca group of companies.

Doc ID-002261449 V7.0

Sponsor

AstraZeneca Pty Ltd

ABN 54 009 682 311

66 Talavera Road

Macquarie Park NSW 2113

Telephone: 1800 805 342

NEXIUM®

Esomeprazole magnesium trihydrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions people ask about NEXIUM. It does not contain all the information that is known about NEXIUM.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking NEXIUM against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What NEXIUM is used for

Reflux Oesophagitis

NEXIUM is taken to treat reflux oesophagitis. This can be caused by "washing back" (reflux) of food and acid from the stomach into the food pipe (oesophagus).

Reflux can cause a burning sensation in the chest rising up to the throat, also known as heartburn.

NEXIUM is also taken to help stop reflux oesophagitis coming back or relapsing.

Upper gastrointestinal symptoms associated with non-steroidal anti-inflammatory drugs (NSAIDs) therapy

NEXIUM is taken to treat the symptoms of pain or discomfort, in the stomach caused by NSAIDs, a type of medicine for pain or inflammation.

NEXIUM is also taken to help heal and prevent ulcers caused by NSAIDs.

Peptic Ulcers Associated with Helicobacter pylori Infection

Most people who have a peptic (gastric and duodenal) ulcer also have a bacterium called *Helicobacter pylori* in their stomach.

Depending on the position of the ulcer it is called a gastric or duodenal ulcer. A gastric ulcer occurs in the stomach. A duodenal ulcer occurs in the duodenum which is the tube leading out from the stomach.

If you have a peptic ulcer, your doctor will prescribe NEXIUM with antibiotics. When NEXIUM and antibiotics are taken together, they work to kill the bacterium and let your ulcer heal. You may need further treatment with antibiotics.

Zollinger-Ellison Syndrome

NEXIUM is also used to treat a rare condition called Zollinger-Ellison syndrome, where the stomach produces large amounts of acid, much more than in ulcers or reflux disease.

Bleeding Peptic Ulcers

When peptic ulcers become severe enough, they start to bleed. You may receive treatment injected into your veins initially. This treatment may be followed with NEXIUM tablets or granules prescribed by your doctor for a longer period of time. This is to help your ulcer/s to heal.

How NEXIUM works

NEXIUM is a type of medicine called a proton-pump inhibitor. It works by decreasing the amount of acid made by the stomach, to give relief of symptoms and allow healing to take place. This does not stop food being digested in the normal way.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

Ask your doctor if you want more information.

Your doctor may have prescribed NEXIUM for another reason.

There is no evidence that NEXIUM is addictive.

Before you take NEXIUM

When you must not take it

Do not take NEXIUM if you have allergies to:

- esomeprazole or any ingredient listed at the end of this leaflet
- any medicines containing a proton-pump inhibitor

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take NEXIUM if you are also taking atazanavir or cilostazol.

Please check with your doctor or pharmacist if you are taking these medicines. These medicines will be affected by NEXIUM.

NEXIUM is not approved for use in children younger than 1 year of age.

There is no specific information about use in children younger than 1 year of age, so NEXIUM is not recommended in these patients.

Do not take NEXIUM after the use by (expiry) date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to take it

You must tell your doctor if you have:

- allergies to any other medicines, foods, dyes or preservatives
- any problems with your liver
- severe kidney problems
- any other medical conditions
- been diagnosed with osteoporosis
- if you have ever had a skin reaction after treatment with a medicine similar to NEXIUM that reduces stomach acid

Do not take NEXIUM if you are pregnant or breastfeeding unless your doctor says so. Ask your doctor about the risks and benefits involved.

It is not known if it is safe for you to take NEXIUM while you are pregnant. It may affect your baby.

It is not known if your baby can take in NEXIUM from breast milk if you are breastfeeding.

Taking other medicines

Do not take NEXIUM if you are taking the following medicines:

- atazanavir and nelfinavir - medicines used to treat viral infections such as HIV
- cilostazol - a medicine used to treat intermittent claudication

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with NEXIUM. These include:

- ketoconazole, itraconazole and voriconazole - medicines used to treat fungal infections
- diazepam - a medicine used to treat anxiety and some other conditions
- phenytoin - a medicine used to treat epilepsy or fits
- citalopram, clomipramine and imipramine - medicines used to treat depression
- St John's wort - a herbal remedy used to treat mood disorders
- clarithromycin and rifampicin - medicines used to treat bacterial infections
- warfarin and clopidogrel - medicines used to prevent blood clots
- digoxin - a medicine used to treat heart conditions
- methotrexate - a medicine used to treat arthritis and some types of cancer
- tacrolimus and mycophenolate mofetil - medicines used to assist in organ transplants
- erlotinib or related medicines used to treat cancer

These medicines may be affected by NEXIUM or may affect how well it works. You may need different amounts of your medicine or you may need to take different medicines. Your doctor can tell you what to do if you are taking any other medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking NEXIUM.

If you have not told your doctor about any of these things, tell them before you take NEXIUM.

How to take NEXIUM

Follow all directions given to you by your doctor and pharmacist carefully.

These instructions may differ from the information contained in this leaflet

If you do not understand the directions on the label, ask your doctor or pharmacist for help.

How to take it

NEXIUM is available as tablets and as granules for suspension in sachets.

NEXIUM Tablets

Take one NEXIUM tablet each day, unless your doctor has told you otherwise.

The dose of NEXIUM tablets is usually 20 mg or 40 mg a day depending on what condition you are being treated for and how severe it is.

Swallow NEXIUM tablets whole with a glass of water. Do not crush or chew the tablets.

If the tablets are chewed or crushed they will not work properly.

If you have difficulty swallowing the tablets:

1. Place the tablet in half a glass of non-carbonated water. Mineral water or other liquids are not suitable.
2. Gently mix the tablet and water by stirring, taking care not to crush the tablet.
3. Stir until the tablet dissolves into little pellets.
4. Drink the liquid with the pellets immediately, or within 30 minutes. Do not chew the pellets.

While you are taking NEXIUM

Things you must do

Take NEXIUM exactly as your doctor has prescribed.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking NEXIUM.

Tell all doctors, dentists and pharmacists who are treating you that you are taking NEXIUM.

Tell your doctor if you become pregnant while you are taking NEXIUM.

Tell your doctor if your symptoms return.

Although NEXIUM can heal ulcers successfully, it may not prevent them recurring at a later date.

If you need to have any medical tests while you are taking NEXIUM, tell your doctor.

It may affect the results of some tests.

Things you must not do

Do not take it to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking NEXIUM.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

- Rinse the glass with half a glass of water and drink.

If you cannot swallow at all, follow steps 1-3 above to disperse the tablets and administer the liquid and pellets through a gastric tube.

NEXIUM Sachets

NEXIUM sachets are usually used for children or adults who have trouble swallowing tablets. The dose of NEXIUM sachets is 10 to 20 mg a day depending on what condition is being treated and how severe it is.

The granules in NEXIUM sachets should be dispersed as follows in non-carbonated water (mineral water is not suitable) before being taken:

- For a 10 mg dose empty the contents of a 10 mg sachet into a glass containing 15 mL of water. For a 20 mg dose empty the contents of two 10 mg sachets into a glass containing 30 mL of water.
- Stir the contents and leave for a few minutes to thicken.
- Stir again and drink within 30 minutes.
- If any material remains after drinking, add more water, stir and drink immediately.

For patients who cannot swallow, NEXIUM granules for oral suspension can be administered via a large syringe through a nasogastric or gastric tube:

- For a 10 mg dose add the contents of a 10 mg sachet to a syringe containing 15 mL of water. For a 20 mg dose add the contents of two 10 mg sachets to a syringe containing 30 mL of water.
- Immediately shake the syringe and leave for a few minutes to thicken.
- Shake the syringe and inject through the nasogastric or gastric tube within 30 minutes.
- Refill the syringe with 15 mL of water, then shake and flush any remaining contents from the

nasogastric or gastric tube into the stomach.

Do not crush or chew the pellets in the suspension.

If the pellets are chewed or crushed they will not work properly.

Take NEXIUM at about the same time each day.

Keeping a regular time for taking NEXIUM will help to remind you to take it.

Keep taking NEXIUM for as long as your doctor recommends.

In most patients, NEXIUM relieves symptoms rapidly and healing is usually complete within 4 weeks. Continue taking NEXIUM for as long as your doctor tells you to.

NEXIUM can be taken with food or on an empty stomach.

If you forget to take it

If you forget to take a dose, take it as soon as you remember, and then go back to taking it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

Taking too much (overdose)

Telephone your doctor or the Poisons Information Centre (13 11 26) or go to Accident and Emergency at your nearest hospital immediately if you think that you or anyone else may have taken too much NEXIUM. Do this even if there are no signs of discomfort or poisoning.

Tell your doctor if you notice any of the following and they worry you:

- nausea or vomiting
- constipation
- diarrhoea
- headache
- wind
- stomach pain
- skin rash, itchy skin
- dizziness
- dry mouth

These side effects are usually mild.

Tell your doctor immediately if you notice any of the following:

- blurred vision
- mood changes, confusion or depression
- muscle pain or weakness, joint pain
- increase in breast size (males)
- increased sweating
- changes in sleep patterns
- fever
- increased bruising
- "pins and needles"
- hair loss
- tremor
- blood in the urine
- skin reaction, especially in sun-exposed areas, with joint pain
- muscle twitching or jerking movements
- irregular (fast or slow) heartbeat
- loss of consciousness or awareness

These side effects may require medical attention.

If you notice any of the following happen, tell your doctor immediately or go to Accident and Emergency at the nearest hospital:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body

- severe skin reaction which may include rash, itching, redness, blistering or peeling of the skin
- signs of liver inflammation including yellowing of the skin or eyes, feeling generally unwell, nausea, vomiting, loss of appetite

These are very serious side effects. You may need urgent medical treatment or hospitalisation.

Occasionally, NEXIUM may be associated with changes in your liver or blood, which may require your doctor to do certain blood tests.

Tell your doctor if you think you have any of these effects or notice anything else that is making you feel unwell.

Some people may get other side effects while taking NEXIUM.

Other problems are more likely to arise from the condition itself rather than the treatment.

For this reason, contact your doctor immediately if you notice any of the following:

- pain or indigestion during treatment with NEXIUM
- you begin to vomit blood or food
- you pass black (blood-stained) motions

Tell your doctor if your reflux symptoms return after you stop taking NEXIUM.

After taking it

Storage

Keep your NEXIUM in the blister pack or sachet until it is time to take it.

If you take NEXIUM out of the blister pack or sachet it will not keep well.

Keep it in a cool, dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on a window sill.

Heat and dampness can destroy some medicines.

Keep NEXIUM where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking NEXIUM or it has passed the expiry date, ask your pharmacist what to do with any left over.

Product description

What NEXIUM looks like

Tablets

NEXIUM 20 mg are light pink, oblong shaped tablets engraved 20 mg on one side and A / EH on the other.

NEXIUM 40 mg are pink, oblong shaped tablets engraved 40 mg on one side and A / EI on the other.

NEXIUM Granules for oral suspension

NEXIUM 10 mg granules for oral suspension are pale yellow fine granules (brownish granules may be visible) in a unit dose sachet.

Ingredients

NEXIUM Tablets

Each NEXIUM tablet contains esomeprazole magnesium trihydrate as the active ingredient equivalent to esomeprazole 20 mg or 40 mg.

Plus, the following inactive ingredients:

- glyceryl monostearate
- hyprolose
- hypromellose
- magnesium stearate
- methacrylic acid copolymer

- microcrystalline cellulose
- synthetic paraffin
- macrogol 6000
- polysorbate 80
- crospovidone
- sodium stearyl fumarate
- purified talc
- titanium dioxide
- triethyl citrate
- sugar spheres (maize starch and sucrose)

The tablets are coloured with iron oxide red CI77491 and/or iron oxide yellow CI77492.

NEXIUM Granules for oral suspension

Each sachet of NEXIUM granules for oral suspension contains esomeprazole magnesium trihydrate as the active ingredient equivalent to esomeprazole 10 mg.

Plus, the following inactive ingredients:

- glyceryl monostearate
- hypolose
- hypromellose
- magnesium stearate
- methacrylic acid copolymer
- polysorbate 80
- talc
- triethyl citrate
- glucose
- xanthan gum
- crospovidone
- citric acid
- iron oxide yellow
- sugar spheres (maize starch and sucrose)

NEXIUM tablets and granules for oral suspension do not contain gluten.

NEXIUM tablets are available in blister packs of 7 (non-marketed) or 30 tablets.

NEXIUM granules are available in packs containing 30 unit dose sachets.

Sponsor

AstraZeneca Pty Ltd
 ABN 54 009 682 311
 66 Talavera Road
 Macquarie Park NSW 2113

Telephone: 1800 805 342

Australian Registration Numbers:
 NEXIUM 20 mg (blister) - 74133
 NEXIUM 40 mg (blister) - 74134
 NEXIUM 10 mg (sachet) - 135726

Non-marketed presentations
 NEXIUM 20 mg (bottle) - 75726
 NEXIUM 40 mg (bottle) - 75727

This leaflet was prepared in December 2022.

NEXIUM® is a registered trade mark of the AstraZeneca group of companies.

Doc ID-002261449 V9.0

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using NEXIUM?

NEXIUM contains the active ingredient esomeprazole magnesium trihydrate. NEXIUM is used to treat Reflux Oesophagitis, Upper gastrointestinal symptoms associated with non-steroidal anti-inflammatory drugs (NSAIDs) therapy, Peptic Ulcers Associated with Helicobacter pylori Infection, Zollinger-Ellison Syndrome and Bleeding Peptic Ulcers.

For more information, see Section [1. Why am I using NEXIUM?](#) in the full CMI.

2. What should I know before I use NEXIUM?

Do not use if you have ever had an allergic reaction to NEXIUM or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use NEXIUM?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with NEXIUM and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use NEXIUM?

- NEXIUM is available as either tablets or as granules for suspension in sachets. The dose of NEXIUM tablets is usually 20 mg or 40 mg a day. The dose of NEXIUM sachets is 10 mg to 20 mg a day. The dose for tablets or sachets depends on what condition you are being treated for and how severe it is.
- Follow all directions given to you by your doctor and pharmacist carefully.

More instructions can be found in Section [4. How do I use NEXIUM?](#) in the full CMI.

5. What should I know while using NEXIUM?

Things you should do	<ul style="list-style-type: none"> • Remind any doctor, dentist or pharmacist you visit that you are using NEXIUM. • Tell your doctor if you become pregnant while you are taking NEXIUM. • Tell your doctor if your symptoms return.
Things you should not do	<ul style="list-style-type: none"> • Do not take NEXIUM to treat any other complaints unless your doctor tells you to. • Do not give this medicine to anyone else, even if their symptoms seem similar to yours.
Driving or using machines	<ul style="list-style-type: none"> • Be careful before you drive or use any machines or tools until you know how NEXIUM affects you.
Looking after your medicine	<ul style="list-style-type: none"> • Keep your NEXIUM in the blister pack or sachet until it is time to take it. • Keep it in a cool, dry place where the temperature stays below 25°C.

For more information, see Section [5. What should I know while using NEXIUM?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. These include nausea or vomiting, constipation, diarrhoea, headache, wind, stomach pain, skin rash, itchy skin, dizziness or dry mouth. However, some serious side effects may need urgent medical attention. These include shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body severe skin reaction which may include rash, itching, redness, blistering or peeling of the skin signs of liver inflammation including yellowing of the skin or eyes, feeling generally unwell, nausea, vomiting, loss of appetite.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

NEXIUM[®]

Active ingredient: *esomeprazole magnesium trihydrate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using NEXIUM. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using NEXIUM.**

Where to find information in this leaflet:

1. [Why am I using NEXIUM?](#)
2. [What should I know before I use NEXIUM?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use NEXIUM?](#)
5. [What should I know while using NEXIUM?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using NEXIUM?

NEXIUM contains the active ingredient esomeprazole magnesium trihydrate. NEXIUM is a type of medicine called a proton-pump inhibitor. It works by decreasing the amount of acid made by the stomach, to give relief of symptoms and allow healing to take place. This does not stop food being digested in the normal way.

Reflux Oesophagitis

NEXIUM is used to treat reflux oesophagitis. This can be caused by "washing back" (reflux) of food and acid from the stomach into the food pipe (oesophagus). Reflux can cause a burning sensation in the chest rising up to the throat, also known as heartburn. NEXIUM is also taken to help stop reflux oesophagitis coming back or relapsing.

Upper gastrointestinal symptoms associated with non-steroidal anti-inflammatory drugs (NSAIDs) therapy

NEXIUM is taken to treat the symptoms of pain or discomfort, in the stomach caused by NSAIDs, a type of medicine for pain or inflammation.

NEXIUM is also taken to help heal and prevent ulcers caused by NSAIDs.

Peptic Ulcers Associated with *Helicobacter pylori* Infection

Most people who have a peptic (gastric and duodenal) ulcer also have a bacterium called *Helicobacter pylori* in their stomach.

Depending on the position of the ulcer it is called a gastric or duodenal ulcer. A gastric ulcer occurs in the stomach. A duodenal ulcer occurs in the duodenum which is the tube leading out from the stomach. If you have a peptic ulcer, your doctor will prescribe NEXIUM with antibiotics. When NEXIUM and antibiotics are taken together, they work to kill the bacterium and let your ulcer heal. You may need further treatment with antibiotics.

Zollinger-Ellison Syndrome

NEXIUM is also used to treat a rare condition called Zollinger-Ellison syndrome, where the stomach produces large amounts of acid, much more than in ulcers or reflux disease.

Bleeding Peptic Ulcers

When peptic ulcers become severe enough, they start to bleed. You may receive treatment injected into your veins initially. This treatment may be followed with NEXIUM tablets or granules prescribed by your doctor for a longer period of time. This is to help your ulcer/s to heal.

2. What should I know before I use NEXIUM?

Warnings

Do not use NEXIUM if:

- you are allergic to esomeprazole magnesium trihydrate, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- you are allergic to any medicines containing proton-pump inhibitors.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not take NEXIUM if you are also taking atazanavir or cilostazol. Please check with your doctor or pharmacist if you are taking these medicines. These medicines will be affected by NEXIUM.

Check with your doctor if you have:

- allergies to any other medicines, foods, dyes or preservatives
- any problems with your liver
- severe kidney problems
- any other medical conditions
- been diagnosed with osteoporosis
- ever had a skin reaction after treatment with a medicine similar to NEXIUM that reduces stomach acid

There is no evidence that NEXIUM is addictive.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

It is not known if it is safe for you to take NEXIUM while you are pregnant. It may affect your baby.

It is not known if your baby can take in NEXIUM from breast milk if you are breastfeeding.

Do not take NEXIUM if you are pregnant or breastfeeding unless your doctor says so. Ask your doctor about the risks and benefits involved.

Children younger than 1 year:

NEXIUM is not approved for use in children younger than 1 year of age. There is no specific information about use in children younger than 1 year of age, so NEXIUM is not recommended in these patients.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking or have recently been taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Do not take NEXIUM if you are taking the following medicines:

- atazanavir and nelfinavir - medicines used to treat viral infections such as HIV
- cilostazol - a medicine used to treat intermittent claudication

Some medicines may interfere with NEXIUM and affect how it works. These include:

- ketoconazole, itraconazole and voriconazole - medicines used to treat fungal infections
- diazepam - a medicine used to treat anxiety and some other conditions
- phenytoin - a medicine used to treat epilepsy or fits
- citalopram, clomipramine and imipramine - medicines used to treat depression
- St John's wort - a herbal remedy used to treat mood disorders
- clarithromycin and rifampicin - medicines used to treat bacterial infections
- warfarin and clopidogrel - medicines used to prevent blood clots
- digoxin - a medicine used to treat heart conditions
- methotrexate - a medicine used to treat arthritis and some types of cancer
- tacrolimus and mycophenolate mofetil - medicines used to assist in organ transplants
- erlotinib or related medicines used to treat cancer

These medicines may be affected by NEXIUM or may affect how well it works. You may need different amounts of

your medicine, or you may need to take different medicines.

Your doctor can tell you what to do if you are taking any other medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect NEXIUM.

4. How do I use NEXIUM?

How much to take

NEXIUM is available as tablets and as granules for suspension in sachets.

NEXIUM Tablets

- Take one NEXIUM tablet each day, unless your doctor has told you otherwise.
- The dose of NEXIUM tablets is usually 20 mg or 40 mg a day depending on what condition you are being treated for and how severe it is.

NEXIUM Sachets

NEXIUM sachets are usually used for children or adults who have trouble swallowing tablets. The dose of NEXIUM sachets is 10 to 20 mg a day depending on what condition is being treated and how severe it is.

- Keep taking NEXIUM for as long as your doctor recommends.
- In most patients, NEXIUM relieves symptoms rapidly and healing is usually complete within 4 weeks.

When to take NEXIUM

- NEXIUM should be used at about the same time each day.
- Keeping a regular time for taking NEXIUM will help to remind you to take it.
- NEXIUM can be taken with food or on an empty stomach.

How to take NEXIUM

Tablets: Swallow NEXIUM tablets whole with a glass of water. Do not crush or chew the tablets. If the tablets are chewed or crushed they will not work properly.

If you have difficulty swallowing the tablets:

1. Place the tablet in half a glass of non-carbonated water. Mineral water or other liquids are not suitable.
2. Gently mix the tablet and water by stirring, taking care not to crush the tablet.
3. Stir until the tablet dissolves into little pellets.
4. Drink the liquid with the pellets immediately, or within 30 minutes. Do not chew the pellets.
5. Rinse the glass with half a glass of water and drink.

If you cannot swallow at all, follow steps 1-3 above to disperse the tablets and administer the liquid and pellets through a gastric tube.

Granules for oral suspension: Do not crush or chew the pellets in the suspension. If the pellets are chewed or crushed, they will not work properly.

The granules in NEXIUM sachets should be dispersed as follows in non-carbonated water (mineral water is not suitable) before being taken:

1. For a 10 mg dose empty the contents of a 10 mg sachet into a glass containing 15 mL of water. For a 20 mg dose empty the contents of two 10 mg sachets into a glass containing 30 mL of water.
2. Stir the contents and leave for a few minutes to thicken.
3. Stir again and drink within 30 minutes.
4. If any material remains after drinking, add more water, stir and drink immediately.

For patients who cannot swallow, NEXIUM granules for oral suspension can be administered via a large syringe through a nasogastric or gastric tube:

1. For a 10 mg dose add the contents of a 10 mg sachet to a syringe containing 15 mL of water. For a 20 mg dose add the contents of two 10 mg sachets to a syringe containing 30 mL of water.
2. Immediately shake the syringe and leave for a few minutes to thicken.
3. Shake the syringe and inject through the nasogastric or gastric tube within 30 minutes.
4. Refill the syringe with 15 mL of water, then shake and flush any remaining contents from the nasogastric or gastric tube into the stomach.

If you forget to use NEXIUM

NEXIUM should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember, and then go back to taking it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you use too much NEXIUM

If you think that you have used too much NEXIUM, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using NEXIUM?

Things you should do

Take NEXIUM exactly as your doctor has prescribed.

If you are about to start on any new medicine, tell your doctor, dentist or pharmacist that you are taking NEXIUM.

Tell all doctors, dentists and pharmacists who are treating you that you are taking NEXIUM.

Tell your doctor if you become pregnant while you are taking NEXIUM.

Tell your doctor if your symptoms return.

Although NEXIUM can heal ulcers successfully, it may not prevent them recurring at a later date.

If you need to have any medical tests while you are taking NEXIUM, tell your doctor.

It may affect the results of some tests.

Things you should not do

- Do not take it to treat any other complaints unless your doctor tells you to.
- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how NEXIUM affects you.

Looking after your medicine

- Keep your NEXIUM in the blister pack or sachet until it is time to take it. If you take NEXIUM out of the blister pack or sachet it will not keep well.
- Keep it in a cool, dry place where the temperature stays below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep NEXIUM where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> nausea or vomiting constipation diarrhoea headache wind stomach pain skin rash, itchy skin dizziness dry mouth 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>
<ul style="list-style-type: none"> blurred vision mood changes, confusion or depression muscle pain or weakness joint pain increase in breast size (males) increased sweating changes in sleep patterns fever increased bruising "pins and needles" hair loss tremor blood in the urine skin reaction, especially in sun-exposed areas, with joint pain muscle twitching or jerking movements irregular (fast or slow) heartbeat loss of consciousness or awareness 	<p>Speak to your doctor immediately if you have any of these side effects.</p> <p>These side effects may require medical attention.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> shortness of breath, wheezing or difficulty breathing swelling of the face, lips, tongue or other parts of the body severe skin reaction which may include rash, itching, redness, blistering or peeling of the skin signs of liver inflammation including yellowing of the skin or eyes, feeling generally unwell, nausea, vomiting, loss of appetite 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>
<ul style="list-style-type: none"> pain or indigestion during treatment with NEXIUM you begin to vomit blood or food you pass black (blood-stained) motions 	<p>Contact your doctor immediately if you notice any of these side effects</p>

Occasionally, NEXIUM may be associated with changes in your liver or blood, which may require your doctor to do certain blood tests.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What NEXIUM contains

Active ingredient (main ingredient)	esomeprazole magnesium trihydrate
Other ingredients (inactive ingredients)	<p>Tablets</p> <ul style="list-style-type: none"> glyceryl monostearate hypromellose hypromellose magnesium stearate methacrylic acid copolymer microcrystalline cellulose synthetic paraffin macrogol 6000 polysorbate 80 crospovidone sodium stearyl fumarate purified talc titanium dioxide triethyl citrate sugar spheres (maize starch and sucrose) <p>The tablets are coloured with iron oxide red C177491 and/or iron oxide yellow C177492.</p> <p>Granules for oral suspension</p> <ul style="list-style-type: none"> glyceryl monostearate hypromellose hypromellose magnesium stearate methacrylic acid copolymer polysorbate 80 purified talc triethyl citrate glucose

	<ul style="list-style-type: none"> • xanthan gum • crospovidone • citric acid • iron oxide yellow • sugar spheres (maize starch and sucrose)
Potential allergens	<ul style="list-style-type: none"> • sorbates

NEXIUM tablets and granules for oral suspension do not contain gluten.

Do not take this medicine if you are allergic to any of these ingredients.

What NEXIUM looks like

Tablets

NEXIUM 20 mg are light pink, oblong shaped tablets engraved 20 mg on one side and A / EH on the other. (AUST R 74133)

NEXIUM 40 mg are pink, oblong shaped tablets engraved 40 mg on one side and A / EI on the other. (AUST R 74134)

NEXIUM Granules for oral suspension

NEXIUM 10 mg granules for oral suspension are pale yellow fine granules (brownish granules may be visible) in a unit dose sachet. (AUST R 135726)

NEXIUM tablets are available in blister packs of 30 tablets.
NEXIUM granules for oral suspension are available in packs containing 30-unit dose sachets.

Who distributes NEXIUM

AstraZeneca Pty Ltd
ABN 54 009 682 311
66 Talavera Road
MACQUARIE PARK NSW 2113

Telephone:- 1800 805 342

This leaflet was prepared in April 2024

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VV-RIM-01378372 V11.0

LOSEC[®] TABLETS

Multiple Unit Pellet System

Omeprazole magnesium

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions people ask about Losec. It does not contain all the information that is known about Losec.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking Losec against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Losec is used for

Reflux Oesophagitis

Losec is used to treat the symptoms of reflux oesophagitis or reflux disease. This can be caused by "washing back" (reflux) of food and acid from the stomach into the food pipe (oesophagus).

Reflux can cause a burning sensation in the chest rising up to the throat, also known as heartburn.

Losec is also taken to help stop reflux oesophagitis coming back or relapsing.

Peptic Ulcers

Losec is used to treat peptic ulcers. Depending on the position of the ulcer it is called a gastric or duodenal

ulcer. A gastric ulcer occurs in the stomach. A duodenal ulcer occurs in the duodenum which is the tube leading out from the stomach.

These ulcers can be caused by too much acid being made in the stomach.

Losec is also used to help stop gastric or duodenal ulcers coming back.

Peptic Ulcers Associated with Helicobacter pylori Infection

Most people who have a peptic ulcer also have a bacterium called Helicobacter pylori in their stomach.

When Losec is taken with antibiotics, they work to kill the bacterium and let your ulcer heal. You may need further treatment with antibiotics.

Peptic Ulcers Associated with Non-steroidal Anti-Inflammatory Drugs (NSAIDs)

Some peptic ulcers are caused by taking medicines called non-steroidal anti-inflammatory drugs (NSAIDs), a type of medicine used to treat pain or inflammation.

Losec is also used to heal and prevent ulcers associated with NSAIDs.

Zollinger-Ellison Syndrome

Losec is also used to treat a rare condition called Zollinger-Ellison syndrome, where the stomach produces large amounts of acid, much more than in ulcers or reflux disease.

How Losec Works

Losec is a type of medicine called a proton-pump inhibitor. It works by decreasing the amount of acid made by the stomach, to give relief of

symptoms and allow healing to take place. This does not stop food being digested in the normal way.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may prescribe this medicine for another reason.

There is no evidence that Losec is addictive.

This medicine is only available on prescription.

Before you take Losec

When you must not take it

Do not take Losec if you have an allergy to:

- omeprazole or any ingredient listed at the end of this leaflet
- any medicine containing a proton-pump inhibitor

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take Losec if you are also taking cilostazol.

Please check with your doctor or pharmacist if you are taking cilostazol. This medicine will be affected by Losec.

Do not take Losec after the use by (expiry) date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should take this medicine, talk to your doctor.

Before you start to take it

You must tell your doctor if you have:

- allergies to any other medicines, foods, dyes or preservatives.
- any problems with your liver
- any other medical conditions

Do not take Losec if you are pregnant or breastfeeding unless your doctor says so. Ask your doctor about the risks and benefits involved.

It is not known if it is safe for you to take Losec while you are pregnant. It may affect your baby.

It is not known if your baby can take in Losec from breast milk if you are breastfeeding.

Taking other medicines

Do not take Losec if you are taking the following medicine:

- cilostazol, a medicine used to treat intermittent claudication.

Tell your doctor if you are taking any other medicines including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Losec Tablets. These include:

- phenytoin - a medicine used to treat epilepsy or fits
- warfarin and clopidogrel - medicines used to prevent blood clots
- digoxin - a medicine used to treat heart conditions
- diazepam - a medicine used to treat anxiety and some other conditions

- St John's wort - a herbal remedy used to treat mood disorders
- ketoconazole, itraconazole, voriconazole - medicines used to treat fungal infection
- medicines to treat infections such as clarithromycin or rifampicin
- atazanavir and nelfinavir - medicines used to treat viral infections such as HIV
- tacrolimus - a medicine used to assist in organ transplants
- methotrexate - a medicine used to treat arthritis and some types of cancer
- erlotinib or related medicines used to treat cancer.

These medicines may be affected by Losec or may affect how well it works. You may need different amounts of your medicine or you may need to take different medicines. Your doctor can tell you what to do if you are taking any other medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

If you have not told your doctor about any of these things, tell them before you take Losec.

How to take Losec

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How to take it

Take one Losec tablet each day, unless your doctor has told you otherwise.

Adults:

The dose of Losec is usually 20 mg a day. The dose may vary from 10 mg

to 40 mg a day depending on what condition you are being treated for and how severe it is.

Children (1 year or older):

The dose of Losec is 10 mg a day for children 10 to 20 kg. This dose may be increased to 20 mg if required. For children more than 20 kg the dose is 20 mg a day. This dose may be increased to 40 mg if required.

Swallow Losec whole with a glass of water. Do not crush or chew the tablets.

If the tablets are chewed or crushed, they will not work properly.

If you have difficulty swallowing the tablets

1. Place the tablet in half a glass of non-carbonated water or fruit juice. Mineral water, carbonated fruit juices, or other liquids are not suitable.
2. Gently mix the tablet and liquid by stirring, taking care not to crush the tablet
3. Stir until the tablet disperses into little pellets
4. Drink the liquid with the pellets immediately, or within 30 minutes. Do not chew the pellets
5. Rinse the glass with half a glass of water and drink.

When to take it

Take Losec at about the same time each day.

Keeping a regular time for taking Losec will help to remind you to take it.

Losec can be taken with food or on an empty stomach.

How long to take it

Keep taking Losec for as long as your doctor recommends.

In most patients, Losec relieves symptoms rapidly and healing is usually complete within 4 weeks. Continue taking Losec for as long as your doctor tells you to.

If you forget to take it

If you forget to take a dose, take it as soon as you remember, and then go back to taking it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (Overdose)

Telephone your doctor or the Poisons Information Centre (13 11 26) or go to Accident and Emergency at your nearest hospital immediately if you think that you or anyone else may have taken too much Losec even if there are no signs of discomfort or poisoning.

While you are taking Losec***Things you must do***

Take Losec exactly as your doctor has prescribed.

If you are about to start any new medicine, remind your doctor and pharmacist that you are taking Losec.

Tell all doctors, dentists and pharmacists who are treating you that you are taking Losec.

Tell your doctor if you become pregnant while you are taking Losec.

Tell your doctor if your symptoms return.

Although Losec can heal ulcers successfully, it may not prevent them recurring at a later date.

If you need to have any medical tests while you are taking Losec, tell your doctor.

It may affect the results of some tests.

Things you must not do

Do not take Losec to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or change the dosage without checking with your doctor.

If you stop taking it suddenly or change the dose, your condition may worsen or you may have unwanted side effects.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Losec.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- constipation
- nausea or vomiting
- diarrhoea
- headache
- skin rash, itchy skin
- wind
- stomach pain
- dizziness
- dry or sore mouth

These side effects are usually mild.

Tell your doctor immediately if you notice any of the following:

- muscle pain or weakness, joint pain
- "pins and needles"
- changes in sleep patterns
- mood changes, confusion or depression
- blurred vision
- increase in breast size (males)
- fever
- increased bruising
- increased sweating
- hair loss
- tremor

These are serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital.

- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in breathing
- shortness of breath or difficulty in breathing
- skin reaction which may include rash, itching, redness, blistering or peeling of the skin
- ulcers, blisters or bleeding of the lips, eyes, mouth, nose and genitals
- blood in the urine
- swelling of hands, feet or ankles
- signs of liver inflammation including yellowing of the skin or eyes, feeling generally unwell, nausea, vomiting, loss of appetite.

These are very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

Occasionally, Losec may be associated with changes in your liver or blood, which may require your doctor to do certain blood tests.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may occur in some people.

Other problems are more likely to arise from the ulcer itself rather than the treatment.

For this reason, contact your doctor immediately if you notice any of the following:

- pain or indigestion that occurs during treatment with Losec
- you begin to vomit blood or food
- you pass black (blood-stained) motions.

After using it

Storage

Keep your Losec in the blister pack until it is time to take them.

If you take Losec out of the blister pack they will not keep well.

Keep it in a cool, dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking Losec or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets you have left over.

Product description

What Losec looks like

Losec 10mg tablets are light pink, oblong shaped, marked with 10mg on one side and a logo on the other side.

Losec 20mg tablets are pink, oblong shaped, marked with 20mg on one side and a logo on the other side.

Ingredients

Each Losec tablet contains omeprazole magnesium as the active ingredient equivalent to omeprazole 10mg or 20mg;

Plus the following inactive ingredients,

- Glyceryl monostearate (E 471)
- Hydroxypropylcellulose
- Hypromellose
- Magnesium stearate (E 572)
- Methacrylic acid copolymer
- Microcrystalline cellulose (E 460)
- Paraffin hard
- Macrogol 6000
- Polysorbate 80 (E 433)
- Crospovidone
- Sodium stearyl fumarate
- Purified talc (E 553(b))
- Titanium dioxide (E 171)
- Triethyl citrate
- Sodium hydroxide
- Sugar spheres (maize starch and sucrose)

The tablets are coloured with iron oxide red CI77491 and/or iron oxide yellow CI77492

Losec are available in blister packs of 30 tablets.

Losec tablets do not contain gluten.

Manufacturer / Distributor

AstraZeneca Pty Ltd
 ABN 54 009 682 311
 Alma Road
 NORTH RYDE NSW 2113

This leaflet was prepared in September 2012.

Australian Registration Number:

Losec Tablets:

10 mg (blister pack) 63414

20 mg (blister pack) 63416

40 mg (blister pack) 63418*

*non-marketed

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LOSEC[®] TABLETS

Multiple Unit Pellet System

Omeprazole magnesium

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions people ask about LOSEC. It does not contain all the information that is known about LOSEC.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking LOSEC against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What LOSEC is used for

Reflux Oesophagitis

LOSEC is used to treat the symptoms of reflux oesophagitis or reflux disease. This can be caused by "washing back" (reflux) of food and acid from the stomach into the food pipe (oesophagus).

Reflux can cause a burning sensation in the chest rising up to the throat, also known as heartburn.

LOSEC is also taken to help stop reflux oesophagitis coming back or relapsing.

Peptic Ulcers

LOSEC is used to treat peptic ulcers. Depending on the position of the ulcer it is called a gastric or duodenal

ulcer. A gastric ulcer occurs in the stomach. A duodenal ulcer occurs in the duodenum which is the tube leading out from the stomach.

These ulcers can be caused by too much acid being made in the stomach.

LOSEC is also used to help stop gastric or duodenal ulcers coming back.

Peptic Ulcers Associated with Helicobacter pylori Infection

Most people who have a peptic ulcer also have a bacterium called Helicobacter pylori in their stomach.

When LOSEC is taken with antibiotics, they work to kill the bacterium and let your ulcer heal.

You may need further treatment with antibiotics.

Peptic Ulcers Associated with Non-steroidal Anti-Inflammatory Drugs (NSAIDs)

Some peptic ulcers are caused by taking medicines called non-steroidal anti-inflammatory drugs (NSAIDs), a type of medicine used to treat pain or inflammation.

LOSEC is also used to heal and prevent ulcers associated with NSAIDs.

Zollinger-Ellison Syndrome

LOSEC is also used to treat a rare condition called Zollinger-Ellison syndrome, where the stomach produces large amounts of acid, much more than in ulcers or reflux disease.

How LOSEC Works

LOSEC is a type of medicine called a proton-pump inhibitor. It works by

decreasing the amount of acid made by the stomach, to give relief of symptoms and allow healing to take place. This does not stop food being digested in the normal way.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may prescribe this medicine for another reason.

There is no evidence that LOSEC is addictive.

This medicine is only available on prescription.

Before you take LOSEC

When you must not take it

Do not take LOSEC if you have an allergy to:

- omeprazole or any ingredient listed at the end of this leaflet
- any medicine containing a proton-pump inhibitor

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take LOSEC if you are also taking cilostazol.

Please check with your doctor or pharmacist if you are taking

cilostazol. This medicine will be affected by LOSEC.

Do not take LOSEC after the use by (expiry) date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should take this medicine, talk to your doctor.

Before you start to take it

You must tell your doctor if you have:

- allergies to any other medicines, foods, dyes or preservatives
- any problems with your liver
- any other medical conditions

Do not take LOSEC if you are pregnant or breastfeeding unless your doctor says so. Ask your doctor about the risks and benefits involved.

It is not known if it is safe for you to take LOSEC while you are pregnant. It may affect your baby.

It is not known if your baby can take in LOSEC from breast milk if you are breastfeeding.

Taking other medicines

Do not take LOSEC if you are taking the following medicine:

- cilostazol - a medicine used to treat intermittent claudication

Tell your doctor if you are taking any other medicines including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with LOSEC Tablets. These include:

- phenytoin - a medicine used to treat epilepsy or fits
- warfarin and clopidogrel - medicines used to prevent blood clots
- digoxin - a medicine used to treat heart conditions

- diazepam - a medicine used to treat anxiety and some other conditions
- St John's wort - a herbal remedy used to treat mood disorders
- ketoconazole, itraconazole, voriconazole - medicines used to treat fungal infection
- clarithromycin or rifampicin - medicines used to treat infections
- atazanavir and nelfinavir - medicines used to treat viral infections such as HIV
- tacrolimus - a medicine used to assist in organ transplants
- methotrexate - a medicine used to treat arthritis and some types of cancer
- erlotinib or related medicines used to treat cancer

These medicines may be affected by LOSEC or may affect how well it works. You may need different amounts of your medicine or you may need to take different medicines. Your doctor can tell you what to do if you are taking any other medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

If you have not told your doctor about any of these things, tell them before you take LOSEC.

How to take LOSEC

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How to take it

Take one LOSEC tablet each day, unless your doctor has told you otherwise.

Adults:

The dose of LOSEC is usually 20 mg a day. The dose may vary from 10 mg to 40 mg a day depending on what condition you are being treated for and how severe it is.

Children (1 year or older):

The dose of LOSEC is 10 mg a day for children 10 to 20 kg. This dose may be increased to 20 mg if required. For children more than 20 kg the dose is 20 mg a day. This dose may be increased to 40 mg if required.

Swallow LOSEC whole with a glass of water. Do not crush or chew the tablets.

If the tablets are chewed or crushed, they will not work properly.

If you have difficulty swallowing the tablets

1. Place the tablet in half a glass of non-carbonated water or fruit juice. Mineral water, carbonated fruit juices, or other liquids are not suitable.
2. Gently mix the tablet and liquid by stirring, taking care not to crush the tablet.
3. Stir until the tablet disperses into little pellets.
4. Drink the liquid with the pellets immediately, or within 30 minutes. Do not chew the pellets
5. Rinse the glass with half a glass of water and drink.

When to take it

Take LOSEC at about the same time each day.

Keeping a regular time for taking LOSEC will help to remind you to take it.

LOSEC can be taken with food or on an empty stomach.

How long to take it

Keep taking LOSEC for as long as your doctor recommends.

In most patients, LOSEC relieves symptoms rapidly and healing is usually complete within 4 weeks.

Continue taking LOSEC for as long as your doctor tells you to.

If you forget to take it

If you forget to take a dose, take it as soon as you remember, and then go back to taking it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (Overdose)

Telephone your doctor or the Poisons Information Centre (13 11 26) or go to Accident and Emergency at your nearest hospital immediately if you think that you or anyone else may have taken too much LOSEC even if there are no signs of discomfort or poisoning.

While you are taking LOSEC

Things you must do

Take LOSEC exactly as your doctor has prescribed.

If you are about to start any new medicine, remind your doctor and pharmacist that you are taking LOSEC.

Tell all doctors, dentists and pharmacists who are treating you that you are taking LOSEC.

Tell your doctor if you become pregnant while you are taking LOSEC.

Tell your doctor if your symptoms return.

Although LOSEC can heal ulcers successfully, it may not prevent them recurring at a later date.

If you need to have any medical tests while you are taking LOSEC, tell your doctor.

It may affect the results of some tests.

Things you must not do

Do not take LOSEC to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or change the dosage without checking with your doctor.

If you stop taking it suddenly or change the dose, your condition may worsen or you may have unwanted side effects.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking LOSEC.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- constipation
- nausea or vomiting
- diarrhoea
- headache
- skin rash, itchy skin
- wind
- stomach pain
- dizziness
- dry or sore mouth

These side effects are usually mild.

Tell your doctor immediately if you notice any of the following:

- muscle pain or weakness, joint pain
- "pins and needles"
- changes in sleep patterns
- mood changes, confusion or depression
- blurred vision
- increase in breast size (males)
- fever
- increased bruising
- increased sweating
- hair loss
- tremor

These are serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital.

- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in breathing
- shortness of breath or difficulty in breathing
- skin reaction which may include rash, itching, redness, blistering or peeling of the skin
- ulcers, blisters or bleeding of the lips, eyes, mouth, nose and genitals
- blood in the urine
- swelling of hands, feet or ankles
- signs of liver inflammation including yellowing of the skin or eyes, feeling generally unwell, nausea, vomiting, loss of appetite

These are very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

Occasionally, LOSEC may be associated with changes in your liver or blood, which may require your doctor to do certain blood tests.

Sponsor

AstraZeneca Pty Ltd
 ABN 54 009 682 311
 Alma Road
 NORTH RYDE NSW 2113

Australian Registration Numbers:
 LOSEC 10 mg (blister pack) - 63414
 LOSEC 20 mg (blister pack) - 63416
 LOSEC 40 mg (blister pack) - 63418*

*non-marketed

This leaflet was prepared in December 2014.

LOSEC® is a registered trade mark of the AstraZeneca group of companies.

Doc ID-001944965 V4.0

Product description

What LOSEC looks like

LOSEC 10 mg tablets are light pink, oblong shaped, marked with 10 mg on one side and a logo on the other side.

LOSEC 20 mg tablets are pink, oblong shaped, marked with 20 mg on one side and a logo on the other side.

Ingredients

Each LOSEC tablet contains omeprazole magnesium as the active ingredient equivalent to omeprazole 10 mg or 20 mg.

Plus the following inactive ingredients:

- Glyceryl monostearate (E 471)
- Hydroxypropylcellulose
- Hypromellose
- Magnesium stearate (E 572)
- Methacrylic acid copolymer
- Microcrystalline cellulose (E 460)
- Paraffin synthetic
- Macrogol 6000
- Polysorbate 80 (E 433)
- Crospovidone
- Sodium stearyl fumarate
- Purified talc (E 553(b))
- Titanium dioxide (E 171)
- Triethyl citrate
- Sodium hydroxide
- Sugar spheres (maize starch and sucrose)

The tablets are coloured with iron oxide red CI77491 and/or iron oxide yellow CI77492.

LOSEC are available in blister packs of 30 tablets.

LOSEC tablets do not contain gluten.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may occur in some people.

Other problems are more likely to arise from the ulcer itself rather than the treatment.

For this reason, contact your doctor immediately if you notice any of the following:

- pain or indigestion that occurs during treatment with LOSEC
- you begin to vomit blood or food
- you pass black (blood-stained) motions

After using it

Storage

Keep your LOSEC in the blister pack until it is time to take them.

If you take LOSEC out of the blister pack they will not keep well.

Keep it in a cool, dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking LOSEC or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets you have left over.

LOSEC[®] TABLETS

Multiple Unit Pellet System

Omeprazole magnesium

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions people ask about LOSEC. It does not contain all the information that is known about LOSEC.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking LOSEC against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What LOSEC is used for

Reflux Oesophagitis

LOSEC is used to treat the symptoms of reflux oesophagitis or reflux disease. This can be caused by "washing back" (reflux) of food and acid from the stomach into the food pipe (oesophagus).

Reflux can cause a burning sensation in the chest rising up to the throat, also known as heartburn.

LOSEC is also taken to help stop reflux oesophagitis coming back or relapsing.

Peptic Ulcers

LOSEC is used to treat peptic ulcers. Depending on the position of the ulcer it is called a gastric or duodenal

ulcer. A gastric ulcer occurs in the stomach. A duodenal ulcer occurs in the duodenum which is the tube leading out from the stomach.

These ulcers can be caused by too much acid being made in the stomach.

LOSEC is also used to help stop gastric or duodenal ulcers coming back.

Peptic Ulcers Associated with Helicobacter pylori Infection

Most people who have a peptic ulcer also have a bacterium called Helicobacter pylori in their stomach.

When LOSEC is taken with antibiotics, they work to kill the bacterium and let your ulcer heal.

You may need further treatment with antibiotics.

Peptic Ulcers Associated with Non-steroidal Anti-Inflammatory Drugs (NSAIDs)

Some peptic ulcers are caused by taking medicines called non-steroidal anti-inflammatory drugs (NSAIDs), a type of medicine used to treat pain or inflammation.

LOSEC is also used to heal and prevent ulcers associated with NSAIDs.

Zollinger-Ellison Syndrome

LOSEC is also used to treat a rare condition called Zollinger-Ellison syndrome, where the stomach produces large amounts of acid, much more than in ulcers or reflux disease.

How LOSEC Works

LOSEC is a type of medicine called a proton-pump inhibitor. It works by

decreasing the amount of acid made by the stomach, to give relief of symptoms and allow healing to take place. This does not stop food being digested in the normal way.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may prescribe this medicine for another reason.

There is no evidence that LOSEC is addictive.

This medicine is only available on prescription.

Before you take LOSEC

When you must not take it

Do not take LOSEC if you have an allergy to:

- omeprazole or any ingredient listed at the end of this leaflet
- any medicine containing a proton-pump inhibitor

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take LOSEC if you are also taking cilostazol.

Please check with your doctor or pharmacist if you are taking

cilostazol. This medicine will be affected by LOSEC.

Do not take LOSEC after the use by (expiry) date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should take this medicine, talk to your doctor.

Before you start to take it

You must tell your doctor if you have:

- allergies to any other medicines, foods, dyes or preservatives
- any problems with your liver
- any other medical conditions

Do not take LOSEC if you are pregnant or breastfeeding unless your doctor says so. Ask your doctor about the risks and benefits involved.

It is not known if it is safe for you to take LOSEC while you are pregnant. It may affect your baby.

It is not known if your baby can take in LOSEC from breast milk if you are breastfeeding.

Taking other medicines

Do not take LOSEC if you are taking the following medicine:

- cilostazol - a medicine used to treat intermittent claudication

Tell your doctor if you are taking any other medicines including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with LOSEC Tablets. These include:

- phenytoin - a medicine used to treat epilepsy or fits
- warfarin and clopidogrel - medicines used to prevent blood clots
- digoxin - a medicine used to treat heart conditions

- diazepam - a medicine used to treat anxiety and some other conditions
- St John's wort - a herbal remedy used to treat mood disorders
- ketoconazole, itraconazole, voriconazole - medicines used to treat fungal infection
- clarithromycin or rifampicin - medicines used to treat infections
- atazanavir and nelfinavir - medicines used to treat viral infections such as HIV
- tacrolimus and mycophenolate mofetil - medicines used to assist in organ transplants
- methotrexate - a medicine used to treat arthritis and some types of cancer
- erlotinib or related medicines used to treat cancer

These medicines may be affected by LOSEC or may affect how well it works. You may need different amounts of your medicine or you may need to take different medicines. Your doctor can tell you what to do if you are taking any other medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

If you have not told your doctor about any of these things, tell them before you take LOSEC.

How to take LOSEC

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How to take it

Take one LOSEC tablet each day, unless your doctor has told you otherwise.

Adults:

The dose of LOSEC is usually 20 mg a day. The dose may vary from 10 mg to 40 mg a day depending on what condition you are being treated for and how severe it is.

Children (1 year or older):

The dose of LOSEC is 10 mg a day for children 10 to 20 kg. This dose may be increased to 20 mg if required. For children more than 20 kg the dose is 20 mg a day. This dose may be increased to 40 mg if required.

Swallow LOSEC whole with a glass of water. Do not crush or chew the tablets.

If the tablets are chewed or crushed, they will not work properly.

If you have difficulty swallowing the tablets

1. Place the tablet in half a glass of non-carbonated water or fruit juice. Mineral water, carbonated fruit juices, or other liquids are not suitable.
2. Gently mix the tablet and liquid by stirring, taking care not to crush the tablet.
3. Stir until the tablet disperses into little pellets.
4. Drink the liquid with the pellets immediately, or within 30 minutes. Do not chew the pellets
5. Rinse the glass with half a glass of water and drink.

When to take it

Take LOSEC at about the same time each day.

Keeping a regular time for taking LOSEC will help to remind you to take it.

LOSEC can be taken with food or on an empty stomach.

How long to take it

Keep taking LOSEC for as long as your doctor recommends.

In most patients, LOSEC relieves symptoms rapidly and healing is usually complete within 4 weeks.

Continue taking LOSEC for as long as your doctor tells you to.

If you forget to take it

If you forget to take a dose, take it as soon as you remember, and then go back to taking it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (Overdose)

Telephone your doctor or the Poisons Information Centre (13 11 26) or go to Accident and Emergency at your nearest hospital immediately if you think that you or anyone else may have taken too much LOSEC even if there are no signs of discomfort or poisoning.

While you are taking LOSEC

Things you must do

Take LOSEC exactly as your doctor has prescribed.

If you are about to start any new medicine, remind your doctor and pharmacist that you are taking LOSEC.

Tell all doctors, dentists and pharmacists who are treating you that you are taking LOSEC.

Tell your doctor if you become pregnant while you are taking LOSEC.

Tell your doctor if your symptoms return.

Although LOSEC can heal ulcers successfully, it may not prevent them recurring at a later date.

If you need to have any medical tests while you are taking LOSEC, tell your doctor.

It may affect the results of some tests.

Things you must not do

Do not take LOSEC to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or change the dosage without checking with your doctor.

If you stop taking it suddenly or change the dose, your condition may worsen or you may have unwanted side effects.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking LOSEC.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- constipation
- nausea or vomiting
- diarrhoea
- headache
- skin rash, itchy skin
- wind
- stomach pain
- dizziness
- dry or sore mouth

These side effects are usually mild.

Tell your doctor immediately if you notice any of the following:

- muscle pain or weakness, joint pain
- "pins and needles"
- changes in sleep patterns
- mood changes, confusion or depression
- blurred vision
- increase in breast size (males)
- fever
- increased bruising
- increased sweating
- hair loss
- tremor

These are serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital.

- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in breathing
- shortness of breath or difficulty in breathing
- skin reaction which may include rash, itching, redness, blistering or peeling of the skin
- ulcers, blisters or bleeding of the lips, eyes, mouth, nose and genitals
- blood in the urine
- swelling of hands, feet or ankles
- signs of liver inflammation including yellowing of the skin or eyes, feeling generally unwell, nausea, vomiting, loss of appetite

These are very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

Occasionally, LOSEC may be associated with changes in your liver or blood, which may require your doctor to do certain blood tests.

Sponsor

AstraZeneca Pty Ltd
 ABN 54 009 682 311
 Alma Road
 NORTH RYDE NSW 2113

Australian Registration Numbers:
 LOSEC 10 mg (blister pack) - 63414
 LOSEC 20 mg (blister pack) - 63416
 LOSEC 40 mg (blister pack) - 63418*

*non-marketed

This leaflet was prepared in June 2015.

LOSEC® is a registered trade mark of the AstraZeneca group of companies.

Doc ID-001944965 V5.0

Product description

What LOSEC looks like

LOSEC 10 mg tablets are light pink, oblong shaped, marked with 10 mg on one side and a logo on the other side.

LOSEC 20 mg tablets are pink, oblong shaped, marked with 20 mg on one side and a logo on the other side.

Ingredients

Each LOSEC tablet contains omeprazole magnesium as the active ingredient equivalent to omeprazole 10 mg or 20 mg.

Plus the following inactive ingredients:

- Glyceryl monostearate (E 471)
- Hydroxypropylcellulose
- Hypromellose
- Magnesium stearate (E 572)
- Methacrylic acid copolymer
- Microcrystalline cellulose (E 460)
- Paraffin synthetic
- Macrogol 6000
- Polysorbate 80 (E 433)
- Crospovidone
- Sodium stearyl fumarate
- Purified talc (E 553(b))
- Titanium dioxide (E 171)
- Triethyl citrate
- Sodium hydroxide
- Sugar spheres (maize starch and sucrose)

The tablets are coloured with iron oxide red CI77491 and/or iron oxide yellow CI77492.

LOSEC are available in blister packs of 30 tablets.

LOSEC tablets do not contain gluten.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may occur in some people.

Other problems are more likely to arise from the ulcer itself rather than the treatment.

For this reason, contact your doctor immediately if you notice any of the following:

- pain or indigestion that occurs during treatment with LOSEC
- you begin to vomit blood or food
- you pass black (blood-stained) motions

After using it

Storage

Keep your LOSEC in the blister pack until it is time to take them.

If you take LOSEC out of the blister pack they will not keep well.

Keep it in a cool, dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking LOSEC or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets you have left over.

LOSEC[®] TABLETS

Multiple Unit Pellet System

Omeprazole magnesium

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions people ask about LOSEC. It does not contain all the information that is known about LOSEC.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking LOSEC against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What LOSEC is used for

Reflux Oesophagitis

LOSEC is used to treat the symptoms of reflux oesophagitis or reflux disease. This can be caused by "washing back" (reflux) of food and acid from the stomach into the food pipe (oesophagus).

Reflux can cause a burning sensation in the chest rising up to the throat, also known as heartburn.

LOSEC is also taken to help stop reflux oesophagitis coming back or relapsing.

Peptic Ulcers

LOSEC is used to treat peptic ulcers. Depending on the position of the ulcer it is called a gastric or duodenal

ulcer. A gastric ulcer occurs in the stomach. A duodenal ulcer occurs in the duodenum which is the tube leading out from the stomach.

These ulcers can be caused by too much acid being made in the stomach.

LOSEC is also used to help stop gastric or duodenal ulcers coming back.

Peptic Ulcers Associated with Helicobacter pylori Infection

Most people who have a peptic ulcer also have a bacterium called Helicobacter pylori in their stomach.

When LOSEC is taken with antibiotics, they work to kill the bacterium and let your ulcer heal.

You may need further treatment with antibiotics.

Peptic Ulcers Associated with Non-steroidal Anti-Inflammatory Drugs (NSAIDs)

Some peptic ulcers are caused by taking medicines called non-steroidal anti-inflammatory drugs (NSAIDs), a type of medicine used to treat pain or inflammation.

LOSEC is also used to heal and prevent ulcers associated with NSAIDs.

Zollinger-Ellison Syndrome

LOSEC is also used to treat a rare condition called Zollinger-Ellison syndrome, where the stomach produces large amounts of acid, much more than in ulcers or reflux disease.

How LOSEC Works

LOSEC is a type of medicine called a proton-pump inhibitor. It works by

decreasing the amount of acid made by the stomach, to give relief of symptoms and allow healing to take place. This does not stop food being digested in the normal way.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may prescribe this medicine for another reason.

There is no evidence that LOSEC is addictive.

This medicine is only available on prescription.

Before you take LOSEC

When you must not take it

Do not take LOSEC if you have an allergy to:

- omeprazole or any ingredient listed at the end of this leaflet
- any medicine containing a proton-pump inhibitor

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take LOSEC if you are also taking cilostazol.

Please check with your doctor or pharmacist if you are taking

cilostazol. This medicine will be affected by LOSEC.

Do not take LOSEC after the use by (expiry) date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should take this medicine, talk to your doctor.

Before you start to take it

You must tell your doctor if you have:

- allergies to any other medicines, foods, dyes or preservatives
- any problems with your liver
- any other medical conditions
- been diagnosed with osteoporosis

Do not take LOSEC if you are pregnant or breastfeeding unless your doctor says so. Ask your doctor about the risks and benefits involved.

It is not known if it is safe for you to take LOSEC while you are pregnant. It may affect your baby.

It is not known if your baby can take in LOSEC from breast milk if you are breastfeeding.

Taking other medicines

Do not take LOSEC if you are taking the following medicine:

- cilostazol - a medicine used to treat intermittent claudication

Tell your doctor if you are taking any other medicines including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with LOSEC Tablets. These include:

- phenytoin - a medicine used to treat epilepsy or fits
- warfarin and clopidogrel - medicines used to prevent blood clots
- digoxin - a medicine used to treat heart conditions

- diazepam - a medicine used to treat anxiety and some other conditions
- St John's wort - a herbal remedy used to treat mood disorders
- ketoconazole, itraconazole, voriconazole - medicines used to treat fungal infection
- clarithromycin or rifampicin - medicines used to treat infections
- atazanavir and nelfinavir - medicines used to treat viral infections such as HIV
- tacrolimus and mycophenolate mofetil - medicines used to assist in organ transplants
- methotrexate - a medicine used to treat arthritis and some types of cancer
- erlotinib or related medicines used to treat cancer

These medicines may be affected by LOSEC or may affect how well it works. You may need different amounts of your medicine or you may need to take different medicines. Your doctor can tell you what to do if you are taking any other medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

If you have not told your doctor about any of these things, tell them before you take LOSEC.

How to take LOSEC

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How to take it

Take one LOSEC tablet each day, unless your doctor has told you otherwise.

Adults:

The dose of LOSEC is usually 20 mg a day. The dose may vary from 10 mg to 40 mg a day depending on what condition you are being treated for and how severe it is.

Children (1 year or older):

The dose of LOSEC is 10 mg a day for children 10 to 20 kg. This dose may be increased to 20 mg if required. For children more than 20 kg the dose is 20 mg a day. This dose may be increased to 40 mg if required.

Swallow LOSEC whole with a glass of water. Do not crush or chew the tablets.

If the tablets are chewed or crushed, they will not work properly.

If you have difficulty swallowing the tablets

1. Place the tablet in half a glass of non-carbonated water or fruit juice. Mineral water, carbonated fruit juices, or other liquids are not suitable.
2. Gently mix the tablet and liquid by stirring, taking care not to crush the tablet.
3. Stir until the tablet disperses into little pellets.
4. Drink the liquid with the pellets immediately, or within 30 minutes. Do not chew the pellets
5. Rinse the glass with half a glass of water and drink.

When to take it

Take LOSEC at about the same time each day.

Keeping a regular time for taking LOSEC will help to remind you to take it.

LOSEC can be taken with food or on an empty stomach.

How long to take it

Keep taking LOSEC for as long as your doctor recommends.

In most patients, LOSEC relieves symptoms rapidly and healing is usually complete within 4 weeks.

Continue taking LOSEC for as long as your doctor tells you to.

If you forget to take it

If you forget to take a dose, take it as soon as you remember, and then go back to taking it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (Overdose)

Telephone your doctor or the Poisons Information Centre (13 11 26) or go to Accident and Emergency at your nearest hospital immediately if you think that you or anyone else may have taken too much LOSEC even if there are no signs of discomfort or poisoning.

While you are taking LOSEC

Things you must do

Take LOSEC exactly as your doctor has prescribed.

If you are about to start any new medicine, remind your doctor and pharmacist that you are taking LOSEC.

Tell all doctors, dentists and pharmacists who are treating you that you are taking LOSEC.

Tell your doctor if you become pregnant while you are taking LOSEC.

Tell your doctor if your symptoms return.

Although LOSEC can heal ulcers successfully, it may not prevent them recurring at a later date.

If you need to have any medical tests while you are taking LOSEC, tell your doctor.

It may affect the results of some tests.

Things you must not do

Do not take LOSEC to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or change the dosage without checking with your doctor.

If you stop taking it suddenly or change the dose, your condition may worsen or you may have unwanted side effects.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking LOSEC.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- constipation
- nausea or vomiting
- diarrhoea
- headache
- skin rash, itchy skin
- wind
- stomach pain
- dizziness
- dry or sore mouth

These side effects are usually mild.

Tell your doctor immediately if you notice any of the following:

- muscle pain or weakness, joint pain
- "pins and needles"
- changes in sleep patterns
- mood changes, confusion or depression
- blurred vision
- increase in breast size (males)
- fever
- increased bruising
- increased sweating
- hair loss
- tremor

These are serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital.

- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in breathing
- shortness of breath or difficulty in breathing
- skin reaction which may include rash, itching, redness, blistering or peeling of the skin
- ulcers, blisters or bleeding of the lips, eyes, mouth, nose and genitals
- blood in the urine
- swelling of hands, feet or ankles
- signs of liver inflammation including yellowing of the skin or eyes, feeling generally unwell, nausea, vomiting, loss of appetite

These are very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

Occasionally, LOSEC may be associated with changes in your liver or blood, which may require your doctor to do certain blood tests.

Sponsor

AstraZeneca Pty Ltd
 ABN 54 009 682 311
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Australian Registration Numbers:
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 LOSEC 20 mg (blister pack) - 63416
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*non-marketed

This leaflet was prepared in July 2015.

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Doc ID-001944965 V6.0

Product description

What LOSEC looks like

LOSEC 10 mg tablets are light pink, oblong shaped, marked with 10 mg on one side and a logo on the other side.

LOSEC 20 mg tablets are pink, oblong shaped, marked with 20 mg on one side and a logo on the other side.

Ingredients

Each LOSEC tablet contains omeprazole magnesium as the active ingredient equivalent to omeprazole 10 mg or 20 mg.

Plus the following inactive ingredients:

- Glyceryl monostearate (E 471)
- Hydroxypropylcellulose
- Hypromellose
- Magnesium stearate (E 572)
- Methacrylic acid copolymer
- Microcrystalline cellulose (E 460)
- Paraffin synthetic
- Macrogol 6000
- Polysorbate 80 (E 433)
- Crospovidone
- Sodium stearyl fumarate
- Purified talc (E 553(b))
- Titanium dioxide (E 171)
- Triethyl citrate
- Sodium hydroxide
- Sugar spheres (maize starch and sucrose)

The tablets are coloured with iron oxide red CI77491 and/or iron oxide yellow CI77492.

LOSEC are available in blister packs of 30 tablets.

LOSEC tablets do not contain gluten.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may occur in some people.

Other problems are more likely to arise from the ulcer itself rather than the treatment.

For this reason, contact your doctor immediately if you notice any of the following:

- pain or indigestion that occurs during treatment with LOSEC
- you begin to vomit blood or food
- you pass black (blood-stained) motions

After using it

Storage

Keep your LOSEC in the blister pack until it is time to take them.

If you take LOSEC out of the blister pack they will not keep well.

Keep it in a cool, dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking LOSEC or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets you have left over.

LOSEC[®] TABLETS

Multiple Unit Pellet System

Omeprazole magnesium

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions people ask about LOSEC. It does not contain all the information that is known about LOSEC.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking LOSEC against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What LOSEC is used for

Reflux Oesophagitis

LOSEC is used to treat the symptoms of reflux oesophagitis or reflux disease. This can be caused by "washing back" (reflux) of food and acid from the stomach into the food pipe (oesophagus).

Reflux can cause a burning sensation in the chest rising up to the throat, also known as heartburn.

LOSEC is also taken to help stop reflux oesophagitis coming back or relapsing.

Peptic Ulcers

LOSEC is used to treat peptic ulcers. Depending on the position of the ulcer it is called a gastric or duodenal

ulcer. A gastric ulcer occurs in the stomach. A duodenal ulcer occurs in the duodenum which is the tube leading out from the stomach.

These ulcers can be caused by too much acid being made in the stomach.

LOSEC is also used to help stop gastric or duodenal ulcers coming back.

Peptic Ulcers Associated with Helicobacter pylori Infection

Most people who have a peptic ulcer also have a bacterium called Helicobacter pylori in their stomach.

When LOSEC is taken with antibiotics, they work to kill the bacterium and let your ulcer heal.

You may need further treatment with antibiotics.

Peptic Ulcers Associated with Non-steroidal Anti-Inflammatory Drugs (NSAIDs)

Some peptic ulcers are caused by taking medicines called non-steroidal anti-inflammatory drugs (NSAIDs), a type of medicine used to treat pain or inflammation.

LOSEC is also used to heal and prevent ulcers associated with NSAIDs.

Zollinger-Ellison Syndrome

LOSEC is also used to treat a rare condition called Zollinger-Ellison syndrome, where the stomach produces large amounts of acid, much more than in ulcers or reflux disease.

How LOSEC Works

LOSEC is a type of medicine called a proton-pump inhibitor. It works by

decreasing the amount of acid made by the stomach, to give relief of symptoms and allow healing to take place. This does not stop food being digested in the normal way.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may prescribe this medicine for another reason.

There is no evidence that LOSEC is addictive.

This medicine is only available on prescription.

Before you take LOSEC

When you must not take it

Do not take LOSEC if you have an allergy to:

- omeprazole or any ingredient listed at the end of this leaflet
- any medicine containing a proton-pump inhibitor

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take LOSEC if you are also taking cilostazol.

Please check with your doctor or pharmacist if you are taking

cilostazol. This medicine will be affected by LOSEC.

Do not take LOSEC after the use by (expiry) date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should take this medicine, talk to your doctor.

Before you start to take it

You must tell your doctor if you have:

- allergies to any other medicines, foods, dyes or preservatives
- any problems with your liver
- any other medical conditions
- been diagnosed with osteoporosis

Do not take LOSEC if you are pregnant or breastfeeding unless your doctor says so. Ask your doctor about the risks and benefits involved.

It is not known if it is safe for you to take LOSEC while you are pregnant. It may affect your baby.

It is not known if your baby can take in LOSEC from breast milk if you are breastfeeding.

Taking other medicines

Do not take LOSEC if you are taking the following medicine:

- cilostazol - a medicine used to treat intermittent claudication

Tell your doctor if you are taking any other medicines including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with LOSEC tablets. These include:

- phenytoin - a medicine used to treat epilepsy or fits
- warfarin and clopidogrel - medicines used to prevent blood clots
- digoxin - a medicine used to treat heart conditions

- diazepam - a medicine used to treat anxiety and some other conditions
- St John's wort - a herbal remedy used to treat mood disorders
- ketoconazole, itraconazole, voriconazole - medicines used to treat fungal infection
- clarithromycin or rifampicin - medicines used to treat infections
- atazanavir and nelfinavir - medicines used to treat viral infections such as HIV
- tacrolimus and mycophenolate mofetil - medicines used to assist in organ transplants
- methotrexate - a medicine used to treat arthritis and some types of cancer
- erlotinib or related medicines used to treat cancer

These medicines may be affected by LOSEC or may affect how well it works. You may need different amounts of your medicine or you may need to take different medicines. Your doctor can tell you what to do if you are taking any other medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

If you have not told your doctor about any of these things, tell them before you take LOSEC.

How to take LOSEC

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How to take it

Take one LOSEC tablet each day, unless your doctor has told you otherwise.

Adults:

The dose of LOSEC is usually 20 mg a day. The dose may vary from 10 mg to 40 mg a day depending on what condition you are being treated for and how severe it is.

Children (1 year or older):

The dose of LOSEC is 10 mg a day for children 10 to 20 kg. This dose may be increased to 20 mg if required. For children more than 20 kg the dose is 20 mg a day. This dose may be increased to 40 mg if required.

Swallow LOSEC whole with a glass of water. Do not crush or chew the tablets.

If the tablets are chewed or crushed, they will not work properly.

If you have difficulty swallowing the tablets

1. Place the tablet in half a glass of non-carbonated water or fruit juice. Mineral water, carbonated fruit juices, or other liquids are not suitable.
2. Gently mix the tablet and liquid by stirring, taking care not to crush the tablet.
3. Stir until the tablet disperses into little pellets.
4. Drink the liquid with the pellets immediately, or within 30 minutes. Do not chew the pellets
5. Rinse the glass with half a glass of water and drink.

When to take it

Take LOSEC at about the same time each day.

Keeping a regular time for taking LOSEC will help to remind you to take it.

LOSEC can be taken with food or on an empty stomach.

How long to take it

Keep taking LOSEC for as long as your doctor recommends.

In most patients, LOSEC relieves symptoms rapidly and healing is usually complete within 4 weeks.

Continue taking LOSEC for as long as your doctor tells you to.

If you forget to take it

If you forget to take a dose, take it as soon as you remember, and then go back to taking it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (Overdose)

Telephone your doctor or the Poisons Information Centre (13 11 26) or go to Accident and Emergency at your nearest hospital immediately if you think that you or anyone else may have taken too much LOSEC even if there are no signs of discomfort or poisoning.

While you are taking LOSEC

Things you must do

Take LOSEC exactly as your doctor has prescribed.

If you are about to start any new medicine, remind your doctor and pharmacist that you are taking LOSEC.

Tell all doctors, dentists and pharmacists who are treating you that you are taking LOSEC.

Tell your doctor if you become pregnant while you are taking LOSEC.

Tell your doctor if your symptoms return.

Although LOSEC can heal ulcers successfully, it may not prevent them recurring at a later date.

If you need to have any medical tests while you are taking LOSEC, tell your doctor.

It may affect the results of some tests.

Things you must not do

Do not take LOSEC to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or change the dosage without checking with your doctor.

If you stop taking it suddenly or change the dose, your condition may worsen or you may have unwanted side effects.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking LOSEC.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- constipation
- nausea or vomiting
- diarrhoea
- headache
- skin rash, itchy skin
- wind
- stomach pain
- dizziness
- dry or sore mouth

These side effects are usually mild.

Tell your doctor immediately if you notice any of the following:

- muscle pain or weakness, joint pain
- "pins and needles"
- changes in sleep patterns
- mood changes, confusion or depression
- blurred vision
- increase in breast size (males)
- fever
- increased bruising
- increased sweating
- hair loss
- tremor

These are serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital.

- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in breathing
- shortness of breath or difficulty in breathing
- skin reaction which may include rash, itching, redness, blistering or peeling of the skin
- ulcers, blisters or bleeding of the lips, eyes, mouth, nose and genitals
- blood in the urine
- swelling of hands, feet or ankles
- signs of liver inflammation including yellowing of the skin or eyes, feeling generally unwell, nausea, vomiting, loss of appetite

These are very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

Occasionally, LOSEC may be associated with changes in your liver or blood, which may require your doctor to do certain blood tests.

ABN 54 009 682 311
66 Talavera Road
MACQUARIE PARK NSW 2113

Telephone: 1800 805 342

Australian Registration Numbers:
LOSEC 10 mg (blister pack) - AUST
R 63414
LOSEC 20 mg (blister pack) - AUST
R 63416
LOSEC 40 mg (blister pack) - AUST
R 63418*

*non-marketed

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December 2017.

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companies.

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Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may occur in some people.

Other problems are more likely to arise from the ulcer itself rather than the treatment.

For this reason, contact your doctor immediately if you notice any of the following:

- pain or indigestion that occurs during treatment with LOSEC
- you begin to vomit blood or food
- you pass black (blood-stained) motions

After using it

Storage

Keep your LOSEC in the blister pack until it is time to take them.

If you take LOSEC out of the blister pack they will not keep well.

Keep it in a cool, dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking LOSEC or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets you have left over.

Product description

What LOSEC looks like

LOSEC 10 mg tablets are light pink, oblong shaped, marked with 10 mg on one side and a logo on the other side.

LOSEC 20 mg tablets are pink, oblong shaped, marked with 20 mg on one side and a logo on the other side.

Ingredients

Each LOSEC tablet contains omeprazole magnesium as the active ingredient equivalent to omeprazole 10 mg or 20 mg.

Plus, the following inactive ingredients:

- Glyceryl monostearate (E 471)
- Hyprollose
- Hypromellose
- Magnesium stearate (E 572)
- Methacrylic acid copolymer
- Microcrystalline cellulose (E 460)
- Synthetic paraffin
- Macrogol 6000
- Polysorbate 80 (E 433)
- Crospovidone
- Sodium stearyl fumarate
- Purified talc (E 553(b))
- Titanium dioxide (E 171)
- Triethyl citrate
- Sodium hydroxide
- Sugar spheres (maize starch and sucrose)

The tablets are coloured with iron oxide red CI77491 and/or iron oxide yellow CI77492.

LOSEC are available in blister packs of 30 tablets.

LOSEC tablets do not contain gluten.

Sponsor

AstraZeneca Pty Ltd

LOSEC[®] TABLETS

Multiple Unit Pellet System

Omeprazole magnesium

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions people ask about LOSEC. It does not contain all the information that is known about LOSEC.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking LOSEC against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What LOSEC is used for

Reflux Oesophagitis

LOSEC is used to treat the symptoms of reflux oesophagitis or reflux disease. This can be caused by "washing back" (reflux) of food and acid from the stomach into the food pipe (oesophagus).

Reflux can cause a burning sensation in the chest rising up to the throat, also known as heartburn.

LOSEC is also taken to help stop reflux oesophagitis coming back or relapsing.

Peptic Ulcers

LOSEC is used to treat peptic ulcers. Depending on the position of the ulcer it is called a gastric or duodenal ulcer. A gastric ulcer occurs in the stomach. A duodenal ulcer occurs in the duodenum which is the tube leading out from the stomach.

These ulcers can be caused by too much acid being made in the stomach.

LOSEC is also used to help stop gastric or duodenal ulcers coming back.

Peptic Ulcers Associated with Helicobacter pylori Infection

Most people who have a peptic ulcer also have a bacterium called Helicobacter pylori in their stomach.

When LOSEC is taken with antibiotics, they work to kill the bacterium and let your ulcer heal. You may need further treatment with antibiotics.

Peptic Ulcers Associated with Non-steroidal Anti-Inflammatory Drugs (NSAIDs)

Some peptic ulcers are caused by taking medicines called non-steroidal anti-inflammatory drugs (NSAIDs), a type of medicine used to treat pain or inflammation.

LOSEC is also used to heal and prevent ulcers associated with NSAIDs.

Zollinger-Ellison Syndrome

LOSEC is also used to treat a rare condition called Zollinger-Ellison syndrome, where the stomach produces large amounts of acid,

much more than in ulcers or reflux disease.

How LOSEC Works

LOSEC is a type of medicine called a proton-pump inhibitor. It works by decreasing the amount of acid made by the stomach, to give relief of symptoms and allow healing to take place. This does not stop food being digested in the normal way.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may prescribe this medicine for another reason.

There is no evidence that LOSEC is addictive.

This medicine is only available on prescription.

Before you take LOSEC

When you must not take it

Do not take LOSEC if you have an allergy to:

- omeprazole or any ingredient listed at the end of this leaflet
- any medicine containing a proton-pump inhibitor

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty

How to take LOSEC

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How to take it

Take one LOSEC tablet each day, unless your doctor has told you otherwise.

Adults:

The dose of LOSEC is usually 20 mg a day. The dose may vary from 10 mg to 40 mg a day depending on what condition you are being treated for and how severe it is.

Children (1 year or older):

The dose of LOSEC is 10 mg a day for children 10 to 20 kg. This dose may be increased to 20 mg if required. For children more than 20 kg the dose is 20 mg a day. This dose may be increased to 40 mg if required.

Swallow LOSEC whole with a glass of water. Do not crush or chew the tablets.

If the tablets are chewed or crushed, they will not work properly.

If you have difficulty swallowing the tablets

1. Place the tablet in half a glass of non-carbonated water or fruit juice. Mineral water, carbonated fruit juices, or other liquids are not suitable.
2. Gently mix the tablet and liquid by stirring, taking care not to crush the tablet.
3. Stir until the tablet disperses into little pellets.
4. Drink the liquid with the pellets immediately, or within 30 minutes. Do not chew the pellets
5. Rinse the glass with half a glass of water and drink.

breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take LOSEC if you are also taking cilostazol.

Please check with your doctor or pharmacist if you are taking cilostazol. This medicine will be affected by LOSEC.

Do not take LOSEC after the use by (expiry) date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should take this medicine, talk to your doctor.

Before you start to take it

You must tell your doctor if you have:

- allergies to any other medicines, foods, dyes or preservatives
- any problems with your liver
- any other medical conditions
- been diagnosed with osteoporosis
- if you have ever had a skin reaction after treatment with a medicine similar to LOSEC that reduces stomach acid

Do not take LOSEC if you are pregnant or breastfeeding unless your doctor says so. Ask your doctor about the risks and benefits involved.

It is not known if it is safe for you to take LOSEC while you are pregnant. It may affect your baby.

It is not known if your baby can take in LOSEC from breast milk if you are breastfeeding.

Taking other medicines

Do not take LOSEC if you are taking the following medicine:

- cilostazol - a medicine used to treat intermittent claudication

Tell your doctor if you are taking any other medicines including any that you buy without a

prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with LOSEC tablets. These include:

- phenytoin - a medicine used to treat epilepsy or fits
- warfarin and clopidogrel - medicines used to prevent blood clots
- digoxin - a medicine used to treat heart conditions
- diazepam - a medicine used to treat anxiety and some other conditions
- St John's wort - a herbal remedy used to treat mood disorders
- ketoconazole, itraconazole, voriconazole - medicines used to treat fungal infection
- clarithromycin or rifampicin - medicines used to treat infections
- atazanavir and nelfinavir - medicines used to treat viral infections such as HIV
- tacrolimus and mycophenolate mofetil - medicines used to assist in organ transplants
- methotrexate - a medicine used to treat arthritis and some types of cancer
- erlotinib or related medicines used to treat cancer

These medicines may be affected by LOSEC or may affect how well it works. You may need different amounts of your medicine or you may need to take different medicines. Your doctor can tell you what to do if you are taking any other medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

If you have not told your doctor about any of these things, tell them before you take LOSEC.

medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- constipation
- nausea or vomiting
- diarrhoea
- headache
- skin rash, itchy skin
- wind
- stomach pain
- dizziness
- dry or sore mouth

These side effects are usually mild.

Tell your doctor immediately if you notice any of the following:

- muscle pain or weakness, joint pain
- "pins and needles"
- changes in sleep patterns
- mood changes, confusion or depression
- blurred vision
- increase in breast size (males)
- fever
- increased bruising
- increased sweating
- hair loss
- tremor

These are serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital.

- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in breathing
- shortness of breath or difficulty in breathing
- skin reaction which may include rash, itching, redness, blistering or peeling of the skin

When to take it

Take LOSEC at about the same time each day.

Keeping a regular time for taking LOSEC will help to remind you to take it.

LOSEC can be taken with food or on an empty stomach.

How long to take it

Keep taking LOSEC for as long as your doctor recommends.

In most patients, LOSEC relieves symptoms rapidly and healing is usually complete within 4 weeks. Continue taking LOSEC for as long as your doctor tells you to.

If you forget to take it

If you forget to take a dose, take it as soon as you remember, and then go back to taking it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (Overdose)

Telephone your doctor or the Poisons Information Centre (13 11 26) or go to Accident and Emergency at your nearest hospital immediately if you think that you or anyone else may have taken too much LOSEC even if there are no signs of discomfort or poisoning.

While you are taking LOSEC

Things you must do

Take LOSEC exactly as your doctor has prescribed.

If you are about to start any new medicine, remind your doctor and pharmacist that you are taking LOSEC.

Tell all doctors, dentists and pharmacists who are treating you that you are taking LOSEC.

Tell your doctor if you become pregnant while you are taking LOSEC.

Tell your doctor if your symptoms return.

Although LOSEC can heal ulcers successfully, it may not prevent them recurring at a later date.

If you need to have any medical tests while you are taking LOSEC, tell your doctor.

It may affect the results of some tests.

Things you must not do

Do not take LOSEC to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or change the dosage without checking with your doctor.

If you stop taking it suddenly or change the dose, your condition may worsen or you may have unwanted side effects.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking LOSEC.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need

- ulcers, blisters or bleeding of the lips, eyes, mouth, nose and genitals
- blood in the urine
- swelling of hands, feet or ankles
- signs of liver inflammation including yellowing of the skin or eyes, feeling generally unwell, nausea, vomiting, loss of appetite
- skin reaction, especially in sun-exposed areas, with joint pain

These are very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

Occasionally, LOSEC may be associated with changes in your liver or blood, which may require your doctor to do certain blood tests.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may occur in some people.

Other problems are more likely to arise from the ulcer itself rather than the treatment.

For this reason, contact your doctor immediately if you notice any of the following:

- pain or indigestion that occurs during treatment with LOSEC
- you begin to vomit blood or food
- you pass black (blood-stained) motions

After using it

Storage

Keep your LOSEC in the blister pack until it is time to take them.

If you take LOSEC out of the blister pack they will not keep well.

Keep it in a cool, dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking LOSEC or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets you have left over.

Product description

What LOSEC looks like

LOSEC 10 mg tablets are light pink, oblong shaped, marked with 10 mg on one side and a logo on the other side.

LOSEC 20 mg tablets are pink, oblong shaped, marked with 20 mg on one side and a logo on the other side.

Ingredients

Each LOSEC tablet contains omeprazole magnesium as the active ingredient equivalent to omeprazole 10 mg or 20 mg, plus the following inactive ingredients:

- Glyceryl monostearate
- Hyprolose
- Hypromellose
- Magnesium stearate
- Methacrylic acid copolymer
- Microcrystalline cellulose
- Synthetic paraffin
- Macrogol 6000
- Polysorbate 80
- Crospovidone
- Sodium stearyl fumarate
- Purified talc
- Titanium dioxide
- Triethyl citrate
- Sodium hydroxide

- Sugar spheres (maize starch and sucrose)

The tablets are coloured with iron oxide red (CI77491) and/or iron oxide yellow (CI77492).

LOSEC are available in blister packs of 30 tablets.

LOSEC tablets do not contain gluten.

Sponsor

AstraZeneca Pty Ltd

ABN 54 009 682 311

66 Talavera Road

MACQUARIE PARK NSW 2113

Telephone: 1800 805 342

Australian Registration Numbers:

LOSEC 10 mg (blister pack) -
AUST R 63414

LOSEC 20 mg (blister pack) -
AUST R 63416

LOSEC 40 mg (blister pack) -
AUST R 63418*

*non-marketed

This leaflet was prepared in March 2019.

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Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I taking LOSEC®?

LOSEC® contains the active ingredient omeprazole (as magnesium). LOSEC® is used to treat: the symptoms of reflux oesophagitis or reflux disease; peptic ulcers; peptic ulcers associated with helicobacter pylori infection; peptic ulcers associated with non-steroidal anti-inflammatory drugs (NSAIDs); and a rare condition called Zollinger-Ellison syndrome.

For more information, see Section [1. Why am I using LOSEC®?](#) in the full CMI.

2. What should I know before I take LOSEC®?

Do not use if you have ever had an allergic reaction to omeprazole magnesium or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use LOSEC®?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with LOSEC® and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take LOSEC®?

- Take one LOSEC® tablet each day, unless your doctor has told you otherwise.
- Swallow LOSEC® whole with a glass of water. Do not crush or chew the tablets.
- If you have difficulty swallowing the tablets, follow the instructions in Section [4. How do I use LOSEC®?](#)

More instructions can be found in Section [4. How do I use LOSEC®?](#) in the full CMI.

5. What should I know while using LOSEC®?

Things you should do	<ul style="list-style-type: none"> • Remind any doctor, dentist or pharmacist you visit that you are using LOSEC®. • Tell your doctor if you become pregnant while you are taking LOSEC®. • Tell your doctor if your symptoms return.
Things you should not do	<ul style="list-style-type: none"> • Do not take LOSEC® to treat any other complaints unless your doctor tells you to. • Do not stop taking your medicine or change the dosage without checking with your doctor.
Driving or using machines	<ul style="list-style-type: none"> • Be careful before you drive or use any machines or tools until you know how LOSEC® affects you.
Drinking alcohol	<ul style="list-style-type: none"> • Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none"> • Keep it in a cool, dry place where the temperature stays below 25°C. • Keep your LOSEC® in the blister pack until it is time to take them.

For more information, see Section [5. What should I know while using LOSEC®?](#) in the full CMI.

6. Are there any side effects?

Mild side effects include: constipation, nausea or vomiting, diarrhoea, wind, stomach pain, headache, dizziness, skin rash, itchy skin, dry or sore mouth.

Serious side effects (Call your doctor straight away, or go straight to the Emergency Department) include: swelling of the face, lips, mouth, tongue or throat, shortness of breath or difficulty in breathing, skin reaction (which may include rash, itching, redness, blistering or peeling of the skin) especially in sun-exposed areas with joint pain, ulcers, blisters or bleeding of the lips, eyes, mouth, nose and genitals, blood in the urine, swelling of hands, feet or ankles, yellowing of the skin or eyes, feeling generally unwell, nausea, vomiting, loss of appetite.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

LOSEC®

Active ingredient(s): *omeprazole magnesium*

Consumer Medicine Information (CMI)

This leaflet provides important information about using LOSEC®. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using LOSEC®.**

Where to find information in this leaflet:

1. [Why am I taking LOSEC®?](#)
2. [What should I know before I use \[medicine name\]?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use \[medicine name\]?](#)
5. [What should I know while using \[medicine name\]?](#)
6. [Are there any side effects?](#)
1. [Why am I taking LOSEC®?](#)
2. [What should I know before I take LOSEC®?](#)
3. [What if I am taking other medicines?](#)
4. [How do I take LOSEC®?](#)
5. [What should I know while using LOSEC®?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I taking LOSEC®?

LOSEC® contains the active ingredient omeprazole (as magnesium). LOSEC® is a type of medicine called a proton-pump inhibitor. It works by decreasing the amount of acid made by the stomach, to give relief of symptoms and allow healing to take place. This does not stop food being digested in the normal way.

Reflux Oesophagitis

LOSEC® is used to treat the symptoms of reflux oesophagitis or reflux disease.

This can be caused by "washing back" (reflux) of food and acid from the stomach into the food pipe (oesophagus).

Reflux can cause a burning sensation in the chest rising up to the throat, also known as heartburn.

LOSEC® is also taken to help stop reflux oesophagitis coming back or relapsing.

Peptic Ulcers

LOSEC® is used to treat peptic ulcers.

Depending on the position of the ulcer it is called a gastric or duodenal ulcer. A gastric ulcer occurs in the stomach. A duodenal ulcer occurs in the duodenum which is the tube leading out from the stomach.

These ulcers can be caused by too much acid being made in the stomach.

LOSEC® is also used to help stop gastric or duodenal ulcers coming back.

Peptic Ulcers Associated with Helicobacter pylori Infection

LOSEC® is used to treat peptic ulcers associated with helicobacter pylori infection.

Most people who have a peptic ulcer also have a bacterium called *Helicobacter pylori* in their stomach.

When LOSEC® is taken with antibiotics, they work to kill the bacterium and let your ulcer heal. You may need further treatment with antibiotics.

Peptic Ulcers Associated with Non-steroidal Anti-Inflammatory Drugs (NSAIDs)

LOSEC® is used to treat peptic ulcers associated with non-steroidal anti-inflammatory drugs (NSAIDs).

Some peptic ulcers are caused by taking medicines called non-steroidal anti-inflammatory drugs (NSAIDs), a type of medicine used to treat pain or inflammation.

LOSEC® is also used to heal and prevent ulcers associated with NSAIDs.

Zollinger-Ellison Syndrome

LOSEC® is also used to treat a rare condition called Zollinger-Ellison syndrome.

This syndrome is where the stomach produces large amounts of acid, much more than in ulcers or reflux disease.

There is no evidence that LOSEC® is addictive.

2. What should I know before I take LOSEC®?

Warnings

Do not take LOSEC® if:

- you are allergic to omeprazole, or any of the ingredients listed at the end of this leaflet.
- you are allergic to any medicine containing a proton pump inhibitor.
- Always check the ingredients to make sure you can use this medicine.
Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.
- you are also taking cilostazol.
Please check with your doctor or pharmacist if you are taking cilostazol. This medicine will be affected by LOSEC®.
- the use by (expiry) date printed on the pack or if the packaging is torn or shows signs of tampering.
If it has expired or is damaged, return it to your pharmacist for disposal.

Check with your doctor if you have:

- allergies to any other medicines, foods, dyes or preservatives.
- take any medicines for any other condition.
- any problems with your liver.

- any other medical conditions.
- been diagnosed with osteoporosis.
- ever had a skin reaction after treatment with a medicine similar to LOSEC® that reduces stomach acid.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not take LOSEC® if you are pregnant or breastfeeding unless your doctor says so. Ask your doctor about the risks and benefits involved.

Check with your doctor if you are pregnant or intend to become pregnant.

It is not known if it is safe for you to take LOSEC® while you are pregnant. It may affect your baby.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

It is not known if your baby can take in LOSEC® from breast milk if you are breastfeeding.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Do not take LOSEC® if you are taking the following medicine:

- cilostazol - a medicine used to treat intermittent claudication.

Some medicines may interfere with LOSEC® and affect how it works.

- phenytoin - a medicine used to treat epilepsy or fits.
- warfarin and clopidogrel - medicines used to prevent blood clots.
- digoxin - a medicine used to treat heart conditions.
- diazepam - a medicine used to treat anxiety and some other conditions.
- St John's wort - a herbal remedy used to treat mood disorders.
- ketoconazole, itraconazole, voriconazole - medicines used to treat fungal infection.
- clarithromycin or rifampicin - medicines used to treat infections.
- atazanavir and nelfinavir - medicines used to treat viral infections such as HIV.
- tacrolimus and mycophenolate mofetil - medicines used to assist in organ transplants.
- methotrexate - a medicine used to treat arthritis and some types of cancer.
- erlotinib or related medicines used to treat cancer.

These medicines may be affected by LOSEC® or may affect how well it works. You may need different amounts of your medicine or you may need to take different

medicines. Your doctor can tell you what to do if you are taking any other medicines.

If you have not told your doctor about any of these things, tell them before you take LOSEC®.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect LOSEC®.

4. How do I take LOSEC®?

How much to take

- Take one LOSEC® tablet each day, unless your doctor has told you otherwise.
- **Adults:** The dose of LOSEC® is usually 20 mg a day. The dose may vary from 10 mg to 40 mg a day depending on what condition you are being treated for and how severe it is.
- **Children (1 year or older):** The dose of LOSEC® is 10 mg a day for children 10 to 20 kg. This dose may be increased to 20 mg if required. For children more than 20 kg the dose is 20 mg a day. This dose may be increased to 40 mg if required.
- Follow the instructions provided and use LOSEC® until your doctor tells you to stop.

When to take LOSEC®

- Take LOSEC® at about the same time each day.
- Keeping a regular time for taking LOSEC® will help to remind you to take it.
- LOSEC® can be taken with food or on an empty stomach.

How to take LOSEC®

- Swallow LOSEC® whole with a glass of water. Do not crush or chew the tablets.
- If the tablets are chewed or crushed, they will not work properly.
- Keep taking LOSEC® for as long as your doctor recommends. In most patients, LOSEC® relieves symptoms rapidly and healing is usually complete within 4 weeks. Continue taking LOSEC® for as long as your doctor tells you to.

If you have difficulty swallowing the tablets:

1. Place the tablet in half a glass of non-carbonated water or fruit juice. Mineral water, carbonated fruit juices, or other liquids are not suitable.
2. Gently mix the tablet and liquid by stirring, taking care not to crush the tablet.
3. Stir until the tablet disperses into little pellets.
4. Drink the liquid with the pellets immediately, or within 30 minutes. Do not chew the pellets.
5. Rinse the glass with half a glass of water and drink.

If you forget to use LOSEC®

LOSEC® should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon

as you remember, and then go back to taking it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you use too much LOSEC®

If you think that you have used too much LOSEC®, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using LOSEC®?

Things you should do

Take LOSEC® exactly as your doctor has prescribed.

If you are about to start any new medicine, remind your doctor and pharmacist that you are taking LOSEC®.

Tell all doctors, dentists and pharmacists who are treating you that you are taking LOSEC®.

Tell your doctor if you become pregnant while you are taking LOSEC®.

Tell your doctor if your symptoms return.

Although LOSEC® can heal ulcers successfully, it may not prevent them recurring at a later date.

If you need to have any medical tests while you are taking LOSEC®, tell your doctor.

It may affect the results of some tests.

Remind any doctor, dentist or pharmacist [you visit that you are using LOSEC®.

Things you should not do

- Do not take LOSEC® to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not stop taking your medicine or change the dosage without checking with your doctor.
If you stop taking it suddenly or change the dose, your condition may worsen or you may have unwanted side effects.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how LOSEC® affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Keep your LOSEC® in the blister pack until it is time to take them.
If you take LOSEC® out of the blister pack they will not keep well.
- Keep it in a cool, dry place where the temperature stays below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Keep it where young children cannot reach it.

When to discard your medicine

If your doctor tells you to stop taking LOSEC® or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets you have left over.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
These side effects are usually mild. <ul style="list-style-type: none"> • constipation • nausea or vomiting • diarrhoea • wind • stomach pain • headache • dizziness • skin rash, itchy skin • dry or sore mouth 	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do

<p>These are serious side effects that may require medical attention. Serious side effects are rare.</p> <ul style="list-style-type: none"> • muscle pain or weakness, joint pain • "pins and needles" • changes in sleep patterns • mood changes, confusion or depression • blurred vision • increase in breast size (males) • fever • increased bruising • increased sweating • hair loss • tremor • pain or indigestion that occurs during treatment with LOSEC® • you begin to vomit blood or food • you pass black (blood-stained) motions 	<p>Tell your doctor immediately if you notice any of these serious side effects.</p>
<p>These are very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.</p> <ul style="list-style-type: none"> • swelling of the face, lips, mouth, tongue or throat which may cause difficulty in breathing • shortness of breath or difficulty in breathing • skin reaction which may include rash, itching, redness, blistering or peeling of the skin • ulcers, blisters or bleeding of the lips, eyes, mouth, nose and genitals • blood in the urine • swelling of hands, feet or ankles • signs of liver inflammation including yellowing of the skin or eyes, feeling generally unwell, nausea, vomiting, loss of appetite • skin reaction, especially in sun-exposed areas, with joint pain 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Occasionally, LOSEC® may be associated with changes in your liver or blood, which may require your doctor to do certain blood tests.

Other problems are more likely to arise from the ulcer itself rather than the treatment.

Tell your doctor if your reflux symptoms return after you stop taking LOSEC®.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What LOSEC® contains

Active ingredient (main ingredient)	Omeprazole magnesium
Other ingredients (inactive ingredients)	Glyceryl monostearate Hyprolose Hypromellose Magnesium stearate Methacrylic acid copolymer Microcrystalline cellulose Synthetic paraffin Macrogol 6000 Polysorbate 80 Crospovidone Sodium stearyl fumarate Purified talc Titanium dioxide Triethyl citrate Sodium hydroxide Sugar spheres (maize starch and sucrose) Iron oxide red (CI77491) Iron oxide yellow (CI77492)

Do not take this medicine if you are allergic to any of these ingredients.

LOSEC® tablets do not contain gluten.

What LOSEC® looks like

LOSEC® 10 mg tablets are light pink, oblong shaped, marked with 10 mg on one side and a logo on the other side.

LOSEC® 20 mg tablets are pink, oblong shaped, marked with 20 mg on one side and a logo on the other side.

Australian Registration Numbers:

LOSEC® 10 mg (blister pack) - AUST R 63414

LOSEC® 20 mg (blister pack) - AUST R 63416

LOSEC® 40 mg (blister pack) - AUST R 63418*

*non-marketed

Who distributes LOSEC®

Pharmaco (Australia) Ltd

Suite 1A, Level 2, 802 Pacific Highway

Gordon NSW 2072

Phone: 1800 201 564

Under license of CHEPLAPHARM Arzneimittel GmbH,
Germany.

This leaflet was prepared in November 2021.



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Bar prints 100mm @ 100%

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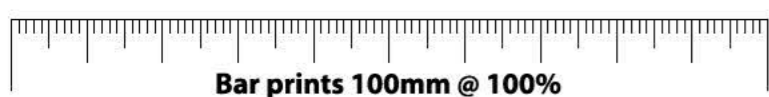
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Dimensions
74 x 30 x 148 mm



Body text size	Smallest text size
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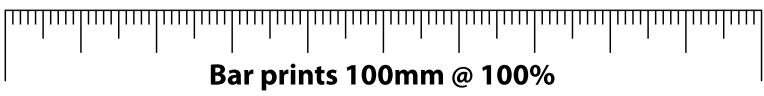
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Created By:	CH			

TEXT AREA



Body text size	Smallest text size
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Regulatory Affairs:	Date:	PMS 130C	PMS 2607C		
Marketing:	Date:	PMS 269C	PMS 2607C(88%)		
		Edition	Revised date		
		B	2011-02-01		



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128

AstraZeneca Pharmaceutical Co., Ltd , No.2, Huangshan Rd, Wuxi, China Tel: + 86 510 85220000 Fax: + 86 510 85227777					
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			A	2012-07-03	



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Marketing:	Date:		PMS 269C	PMS 370C	
			PMS 2607C(88%)		
			Edition	Revised date	
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Regulatory				
Marketing				
Medical				
Other	s22			3/2/11
D2				Date approved:

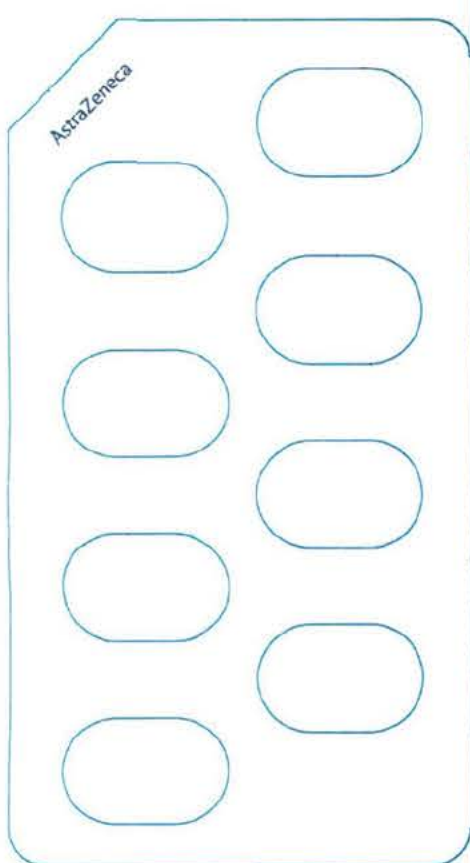
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			Edtion	Revised date	
			B	2011-02-01	



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Department	Regulatory	Signature	Date
Marketing			
Medical			
Other			
Date submitted:		Date approved:	

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Regulatory Affairs: s22	Date: 2/2/11				
Marketing: s22	Date: 2/02/11				
			Edition	Revised date	
			B	2011-02-01	



Nexium[®] 20 mg
esomeprazole
Multiple Unit Pellet System

Please ask your pharmacist for information about this medicine. Consumer medicine information is also available at www.astrazeneca.com.au/CMI



Made in Sweden
Store below 25°C

AstraZeneca Pty Ltd
Alma Road, North Ryde NSW 2113 Australia
www.astrazeneca.com.au

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Nexium is a trade mark of the AstraZeneca group of companies

PRESCRIPTION ONLY MEDICINE
KEEP OUT OF REACH OF CHILDREN


Nexium[®] 20 mg
esomeprazole
Multiple Unit Pellet System

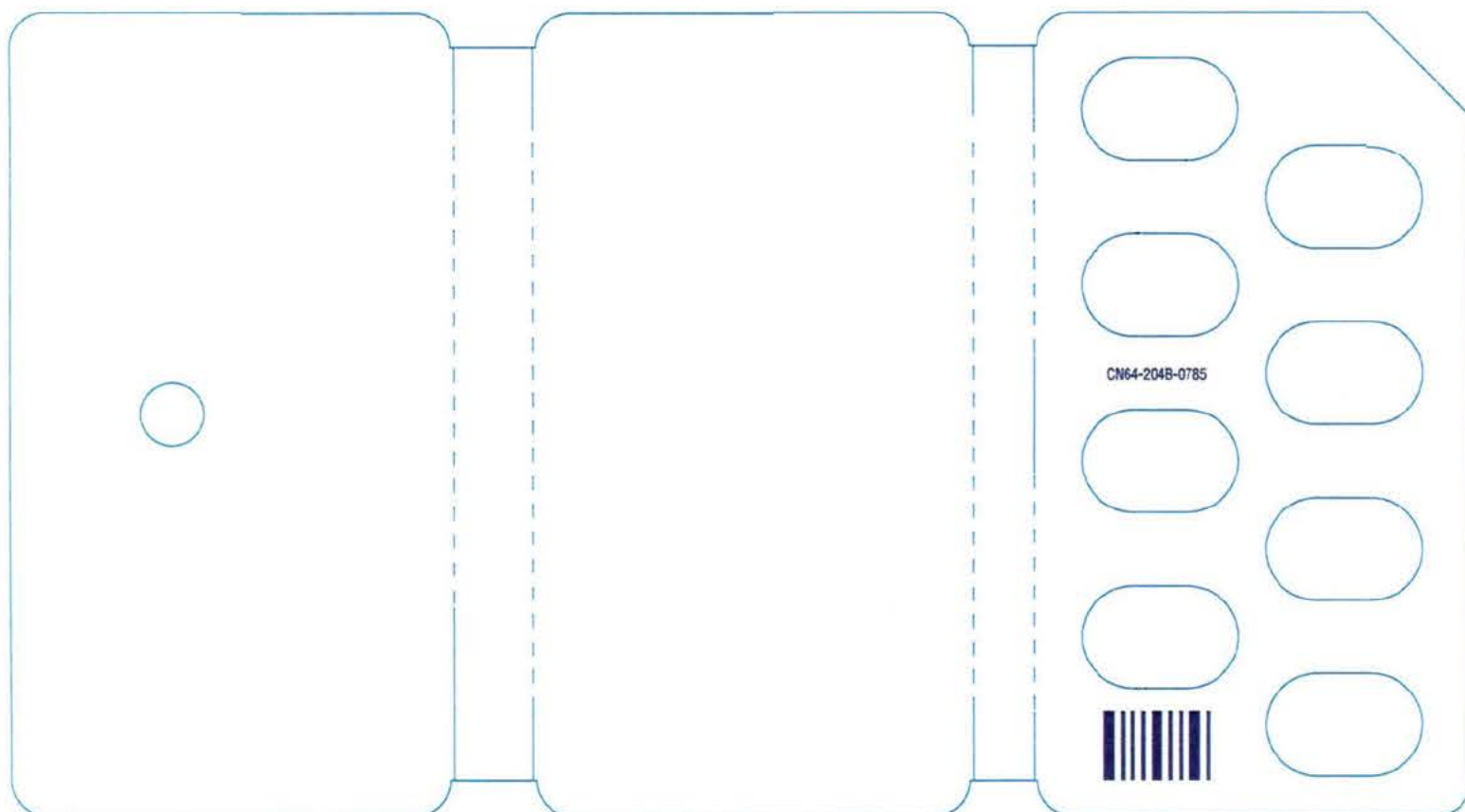
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Each tablet contains
esomeprazole (equivalent to esomeprazole 20 mg)
Use as directed by physician.

15 enteric coated tablets

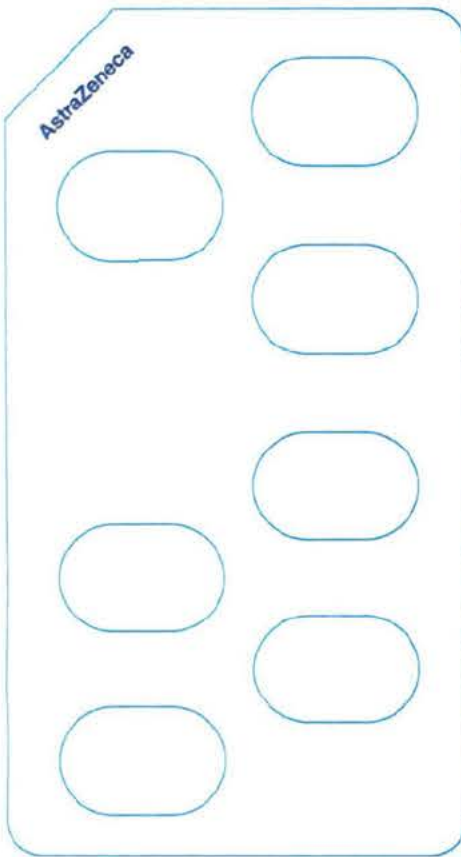
AUST R 74133
Reorder 03184






Department	Regulatory	Marketing	Medical	Other	Date approved:
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Signature					s22

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			Edition	Revised date	
			A	2011-01-20	



Nexium[®] 20_{mg}
esomeprazole
Multiple Unit Pellet System

Please ask your doctor for information about this medicine.
Consumer medicine information is also available at www.astrazeneca.com.au/TAM



9 322882 006583

Unlicensed area

Name and telephone number of Medical Practitioner: _____

Name of patient: _____

Dosage instructions: _____

Date: ____/____/____

AstraZeneca Pty Ltd
Alpha Road, North Ryde NSW 2113 Australia
www.astrazeneca.com.au

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LOT 12045678
EXP 04/2012

PRESCRIPTION ONLY MEDICINE
KEEP OUT OF REACH OF CHILDREN

Nexium[®] 20_{mg}
esomeprazole
Multiple Unit Pellet System

Open here

Each tablet contains:
esomeprazole magnesium trihydrate 22.3 mg
Equivalent to: esomeprazole 20 mg
Use as directed by physician

Made in Sweden
Store below 25 °C

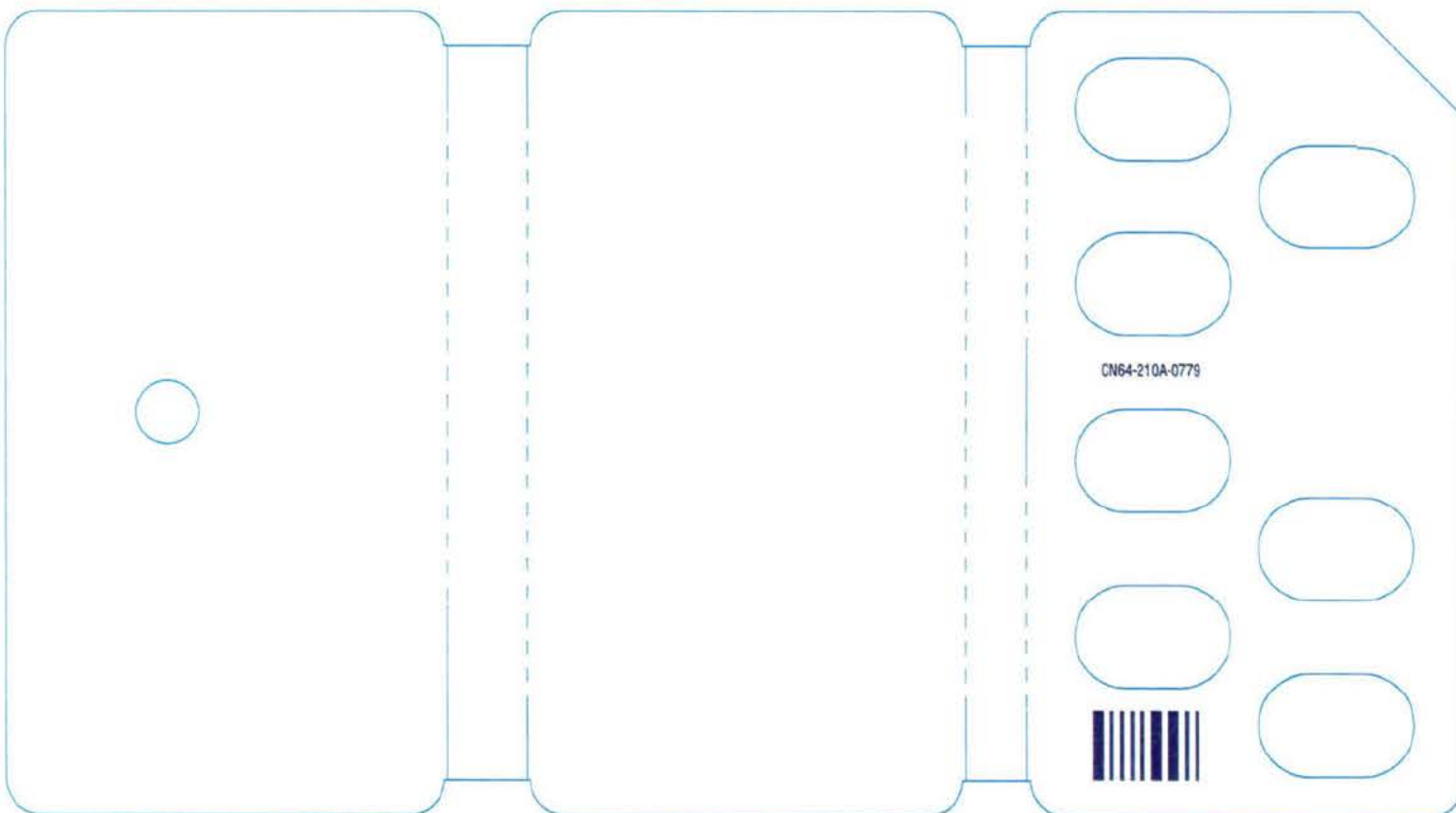
Sample only - not for sale

7 enteric coated tablets

AUST R 74133
Reorder 03182

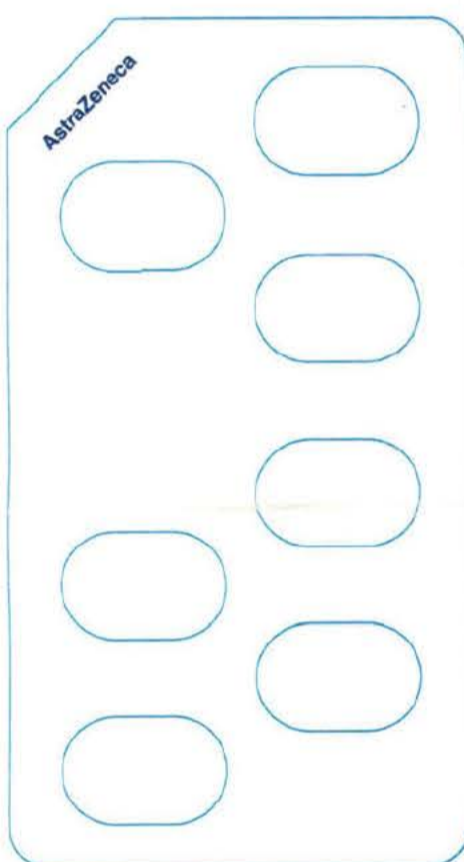
AstraZeneca

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Department	Regulatory	Marketing	Medical	Other:	Date approved:
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Regulatory Affairs:	Date: 2/2/11				
Marketing:	Date: 2/2/11		Edition: A Revised date: 2011-01-14		



Nexium 20mg
esomeprazole
Multiple Unit Pellet System

Please ask your pharmacist for information about this medicine.
Consumer medicine information is also available at
www.astrazeneca.com.au/CMI

AstraZeneca Pty Ltd
Atco Road, North Ryde NSW 2113 Australia
www.astrazeneca.com.au

© AstraZeneca 2010
Nexium is a trade mark of the AstraZeneca group of companies.

LOT 1045578
EXP 08/2011

PRESCRIPTION ONLY MEDICINE
KEEP OUT OF REACH OF CHILDREN

Nexium 20mg
esomeprazole
Multiple Unit Pellet System

Open here

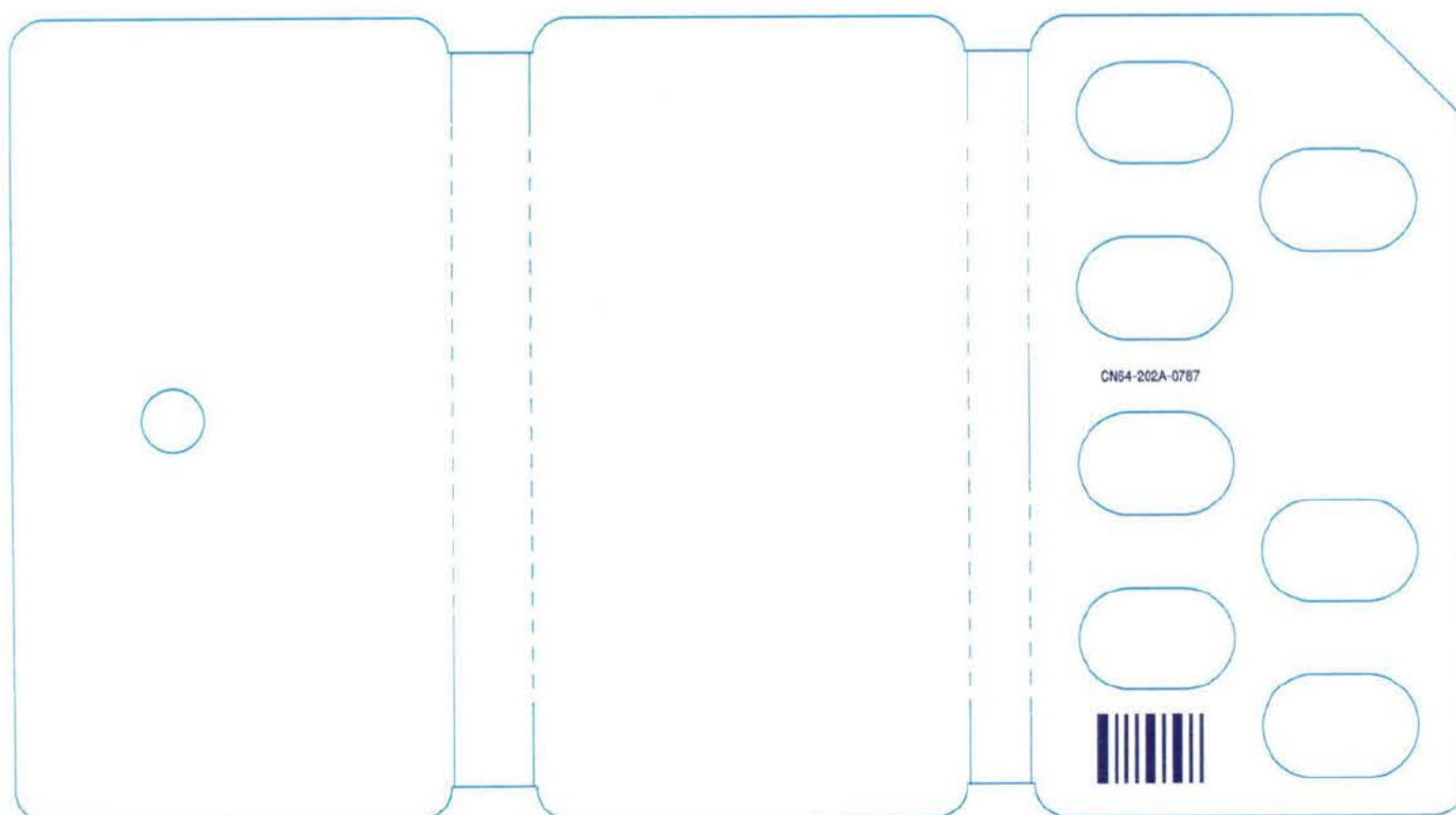
Each tablet contains:
esomeprazole magnesium trihydrate 22.3 mg
Equivalent to esomeprazole 20 mg
Use as directed by physician.

Made in Sweden
Store below 25°C

7 enteric coated tablets

AUST R 74133
Reorder 03183

AstraZeneca



Hospital pack

Date					3/2/11
Signature					s22
Department	Regulatory	Marketing	Medical	Other	

AstraZeneca Pharmaceutical Co., Ltd , No.2, Huangshan Rd, Wuxi, China Tel: + 86 510 85220000 Fax: + 86 510 85227777					
PM name:	Article No.	PHARM code:	Scale	Flutter Mark	Dimensions: (mm)
Unit Carton for Nexium 40mg 30s(AU)	CN63-480	7805	100%	37.58	70x32x136
Designer /Date	s22 2011-01-24		Checker/ Date		
Approval Authority Signed			Colours used in Artwork		
Legal Affairs:	Date:		Does not print		
Regulatory Affairs:	s22 Date: 2/2/11		PMS 130C	PMS 2607C	
Marketing:	s22 Date: 2/4/11		PMS 269C	PMS 370C	
			PMS 2607C(88%)		
			Edition	Revised date	
			B	2011-02-01	

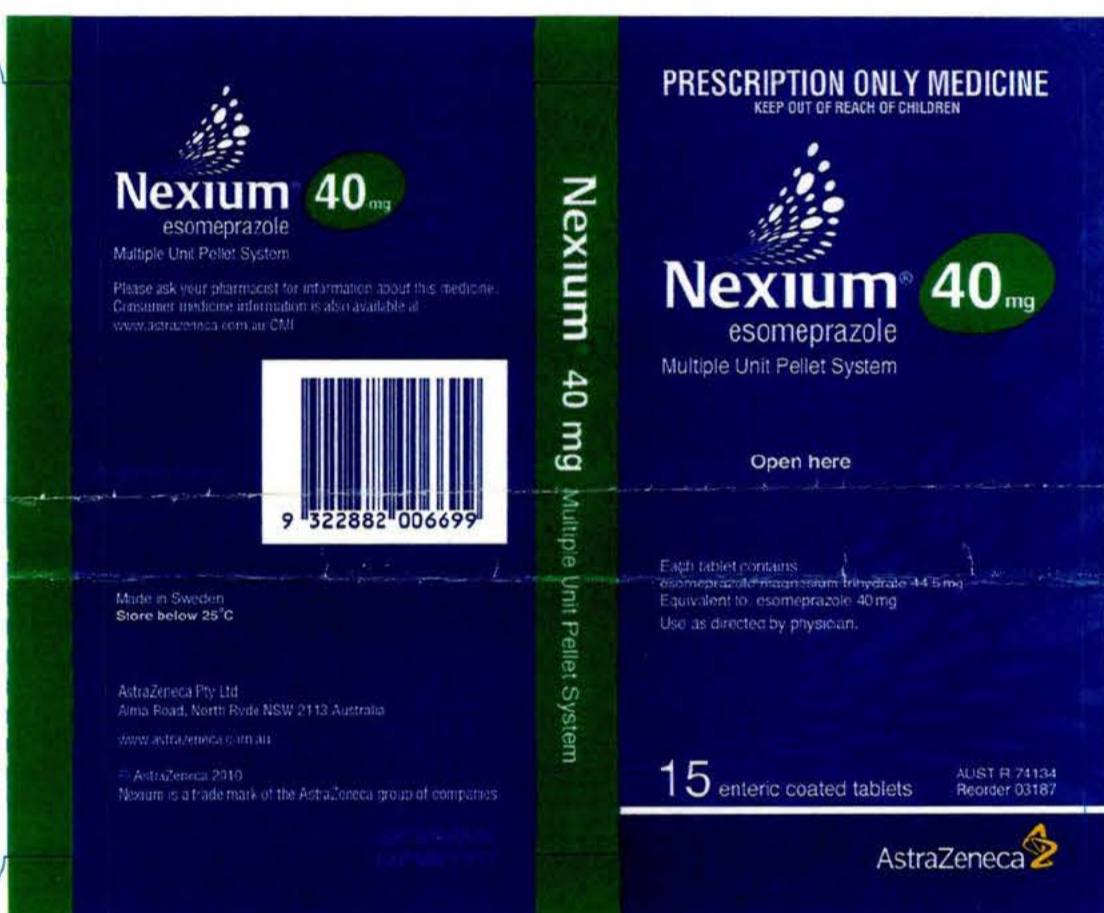
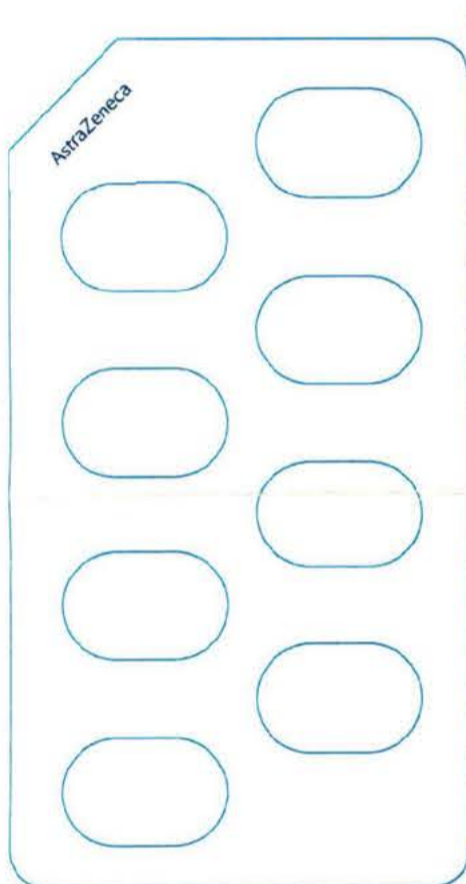


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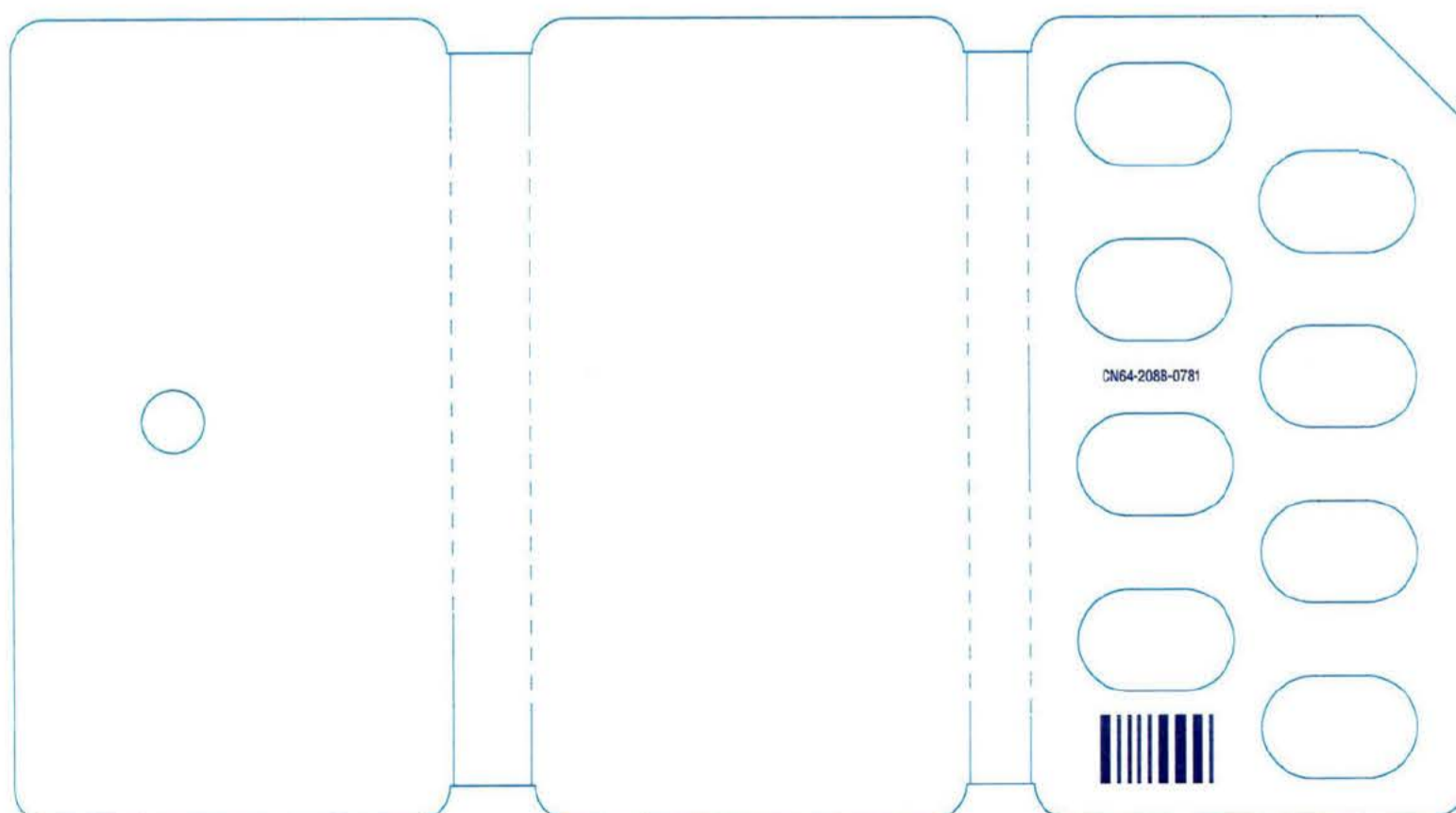
Department	Regulatory	Marketing	Medical	Other	Date
				code 3187 = Nex 40mg / 30 Tabs 93 22882 00 6026 3/12/11	
Signature					Date approved

AstraZeneca Pharmaceutical Co., Ltd., No.2, Huangshan Rd, Wuxi, China Tel: + 86 510 85220000 Fax: + 86 510 85227777

PM name: Wallet Card for Nexium 40mg 15s(AU)	Article No.: CN64-208	PHARM code: 0781	Scale: 100%	Flutter Mark	Dimensions: (mm) 212.8x116
Designer /Date s22 2011-01-21			Checker/ Date		
Approval Authority Signed			Colours used in Artwork		
Legal Affairs:		Date:		<input type="checkbox"/> Does not print <input type="checkbox"/> PMS 130C <input type="checkbox"/> PMS 2607C <input type="checkbox"/> PMS 269C <input type="checkbox"/> PMS 370C <input type="checkbox"/> PMS 2607C(88%)	
Regulatory Affairs: s22		Date: 2/2/11			
Marketing: s22		Date: 2/2/11			
			Edtion	Revised date	
			B	2011-02-01	

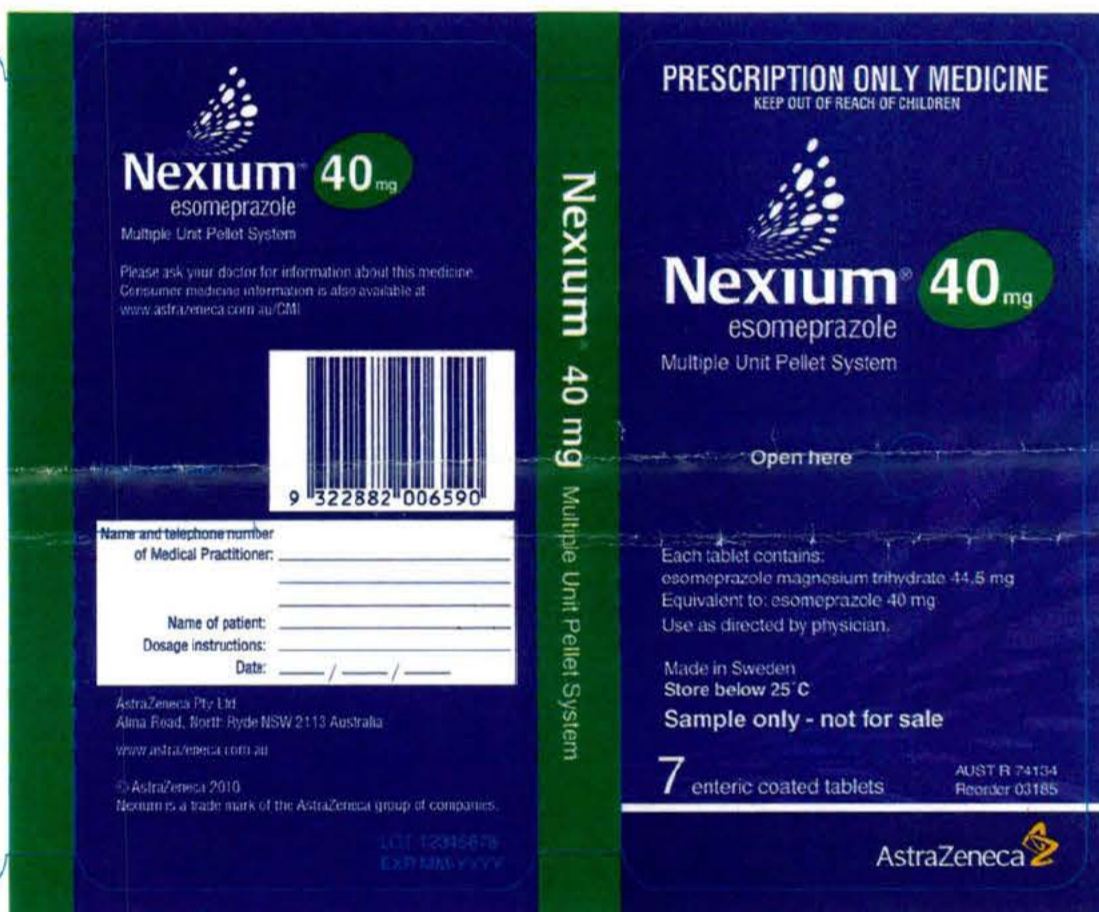
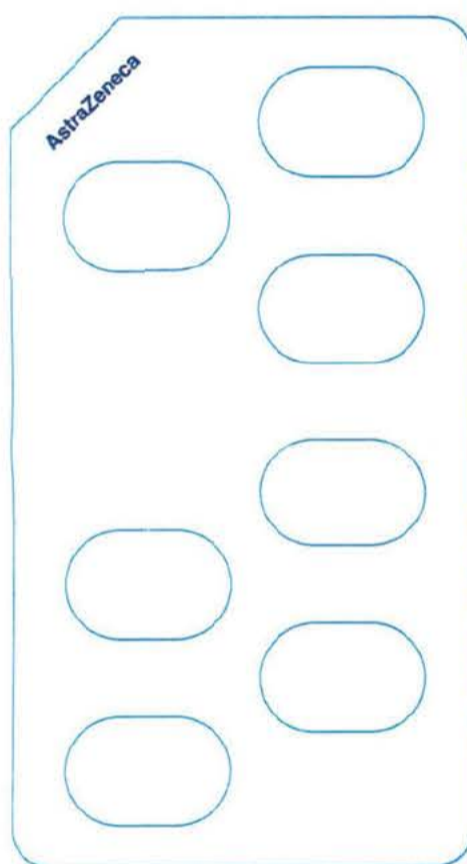


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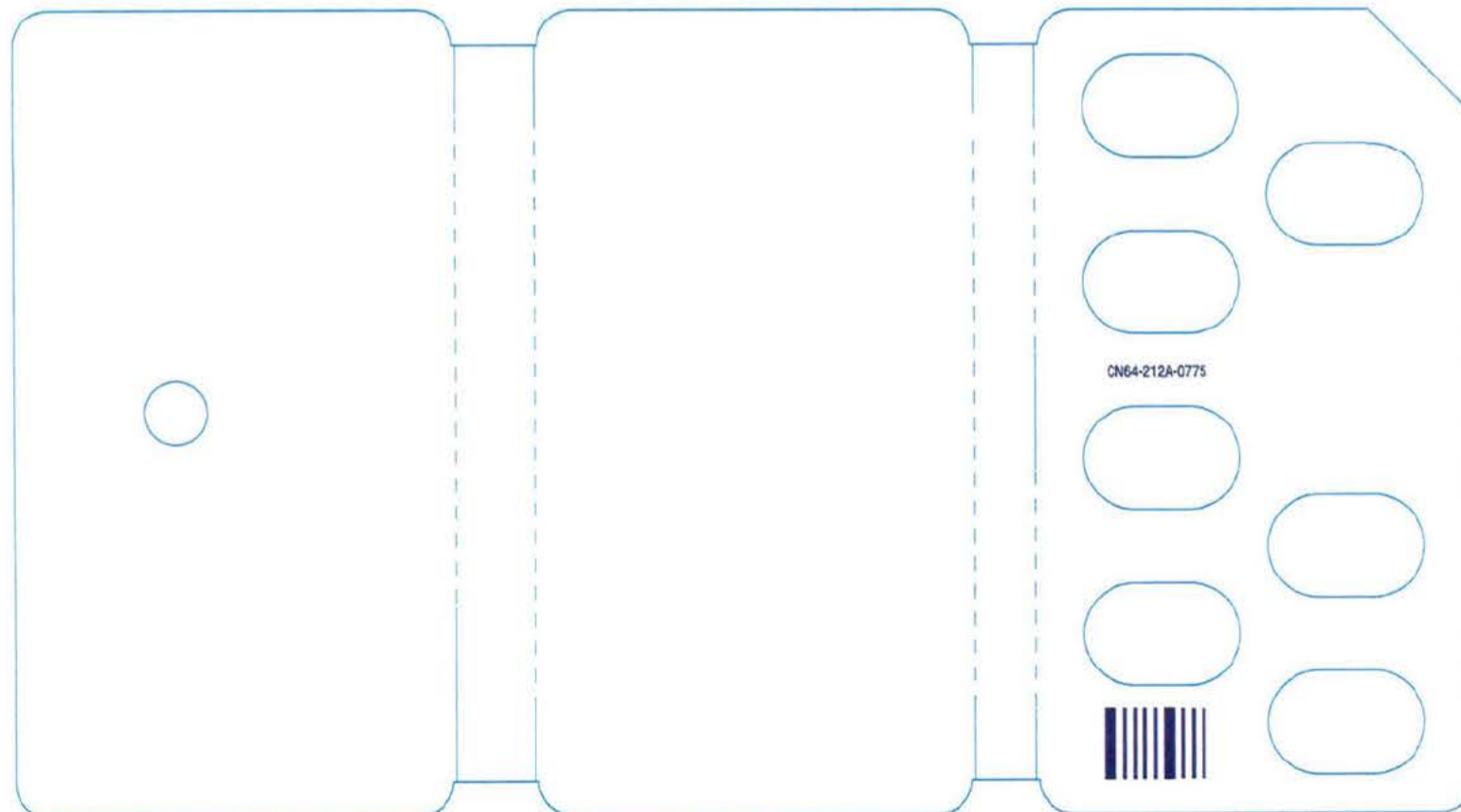


Department	Regulatory	Marketing	Medical	Other	Date
					3/2/11
Signature					Date approved:
Date submitted:					

AstraZeneca Pharmaceutical Co., Ltd., No.2, Huangshan Rd, Wuxi, China Tel: + 86 510 85220000 Fax: + 86 510 85227777					
PM name:	Article No.	PHARM code:	Scale	Flutter Mark	Dimensions: (mm)
Wallet Card for Nexium 40mg 7s(sample)	CN64-212	0775	100%		212.8x116
Designer /Date	s22 / 2011-01-20			Checker/ Date	
Approval Authority Signed			Colours used in Artwork		
Legal Affairs:	Date:		<input type="checkbox"/> Does not print <input type="checkbox"/> PMS 130C <input type="checkbox"/> PMS 2607C <input type="checkbox"/> PMS 269C <input type="checkbox"/> PMS 370C <input type="checkbox"/> PMS 2607C(88%)		
Regulatory Affairs:	Date: 2/2/11				
Marketing:	Date: 2-2-11				
Edition			Revised date		
A			2011-01-20		



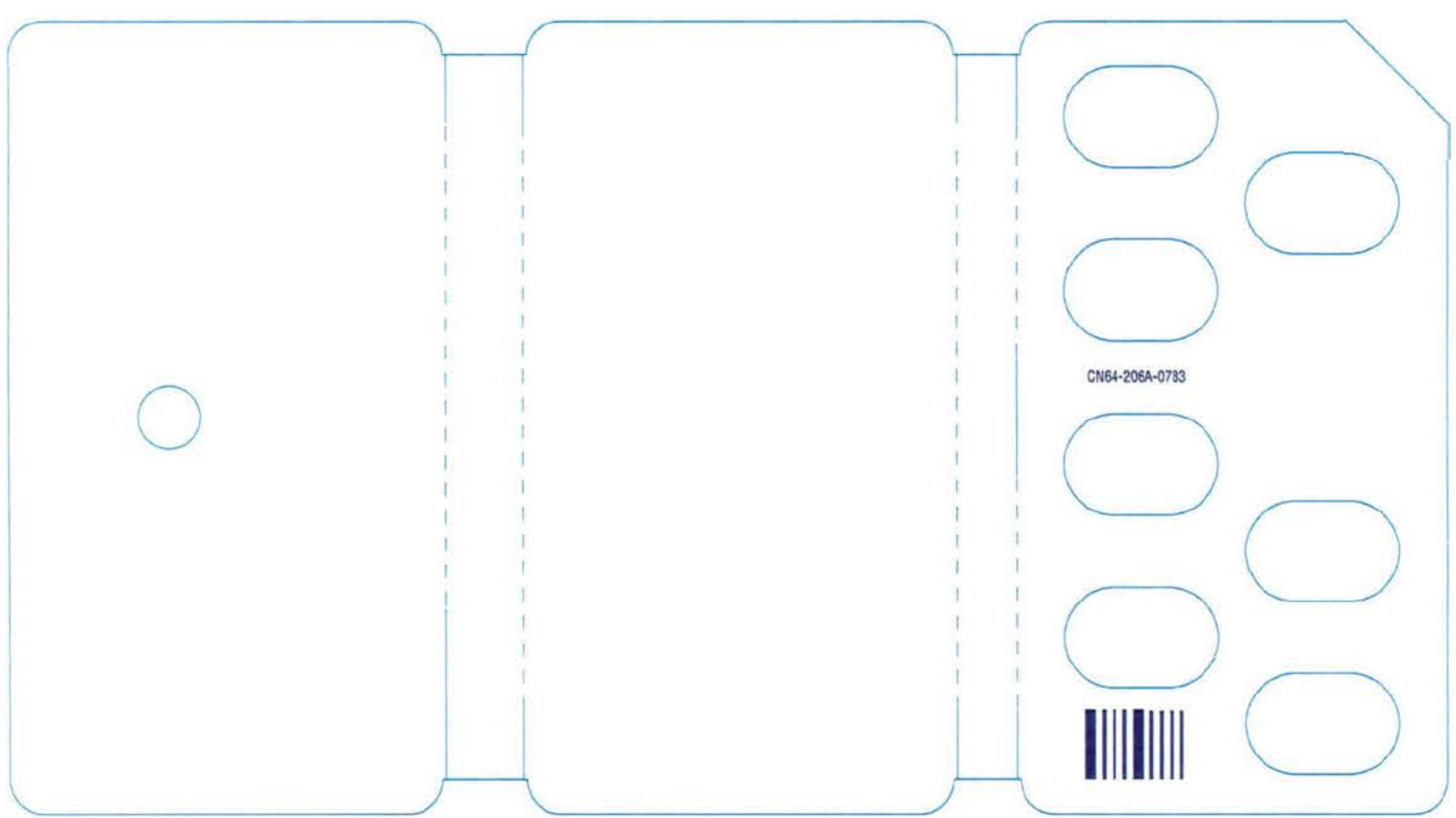
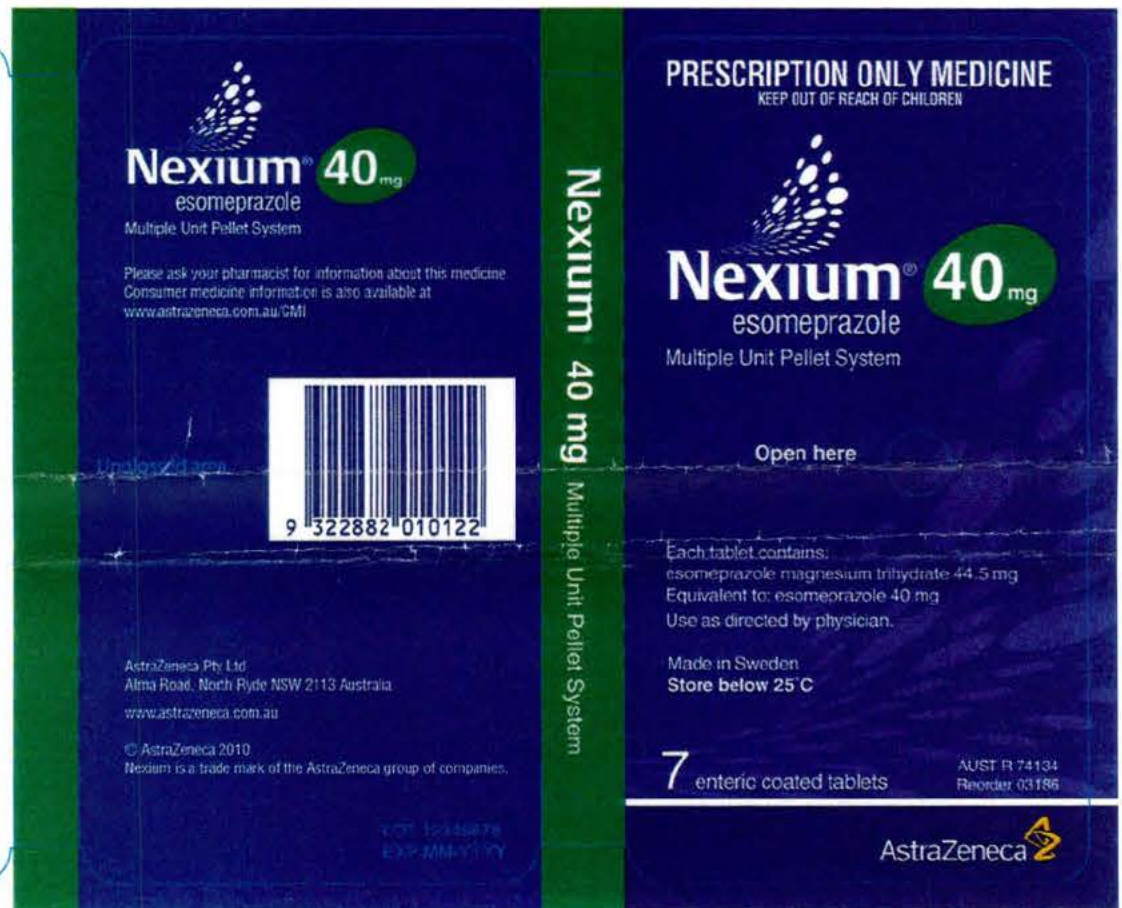
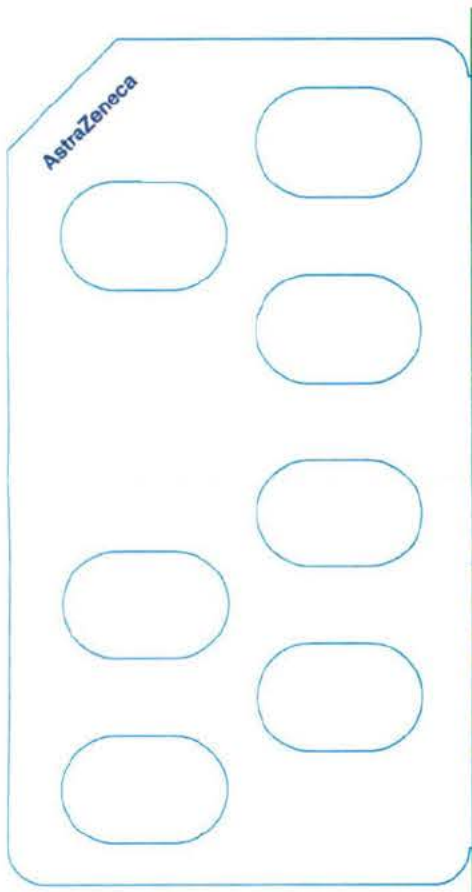
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Sample

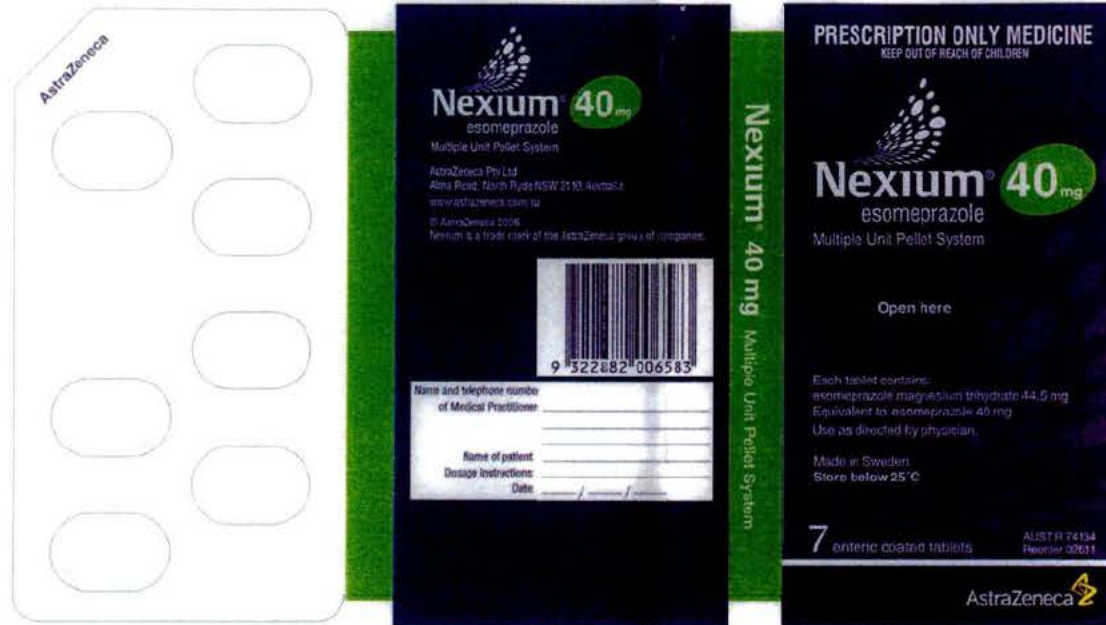
Department	Regulatory	Marketing	Medical	Other	Date
					3/2/11
Signature					Date approved:
s22					

AstraZeneca Pharmaceutical Co., Ltd., No.2, Huangshan Rd, Wuxi, China Tel: + 86 510 85220000 Fax: + 86 510 85227777					
PM name:	Article No.	PHARM code:	Scale	Flutter Mark	Dimensions: (mm)
Wallet Card for Nexium 40mg 7s(sales)	CN64-206	0783	100%		212.8x116
Designer /Date	s22 / 2011-01-20			Checker/ Date	
Approval Authority Signed			Colours used in Artwork		
Legal Affairs:	Date:		<input type="checkbox"/> Does not print <input type="checkbox"/> PMS 130C <input type="checkbox"/> PMS 2607C <input type="checkbox"/> PMS 269C <input type="checkbox"/> PMS 370C <input type="checkbox"/> PMS 2607C(88%)		
Regulatory Affairs:	Date: 2/2/11				
Marketing:	Date: 2/2/11				
Edition			Revised date		
A			2011-01-20		



77

Handwritten signature

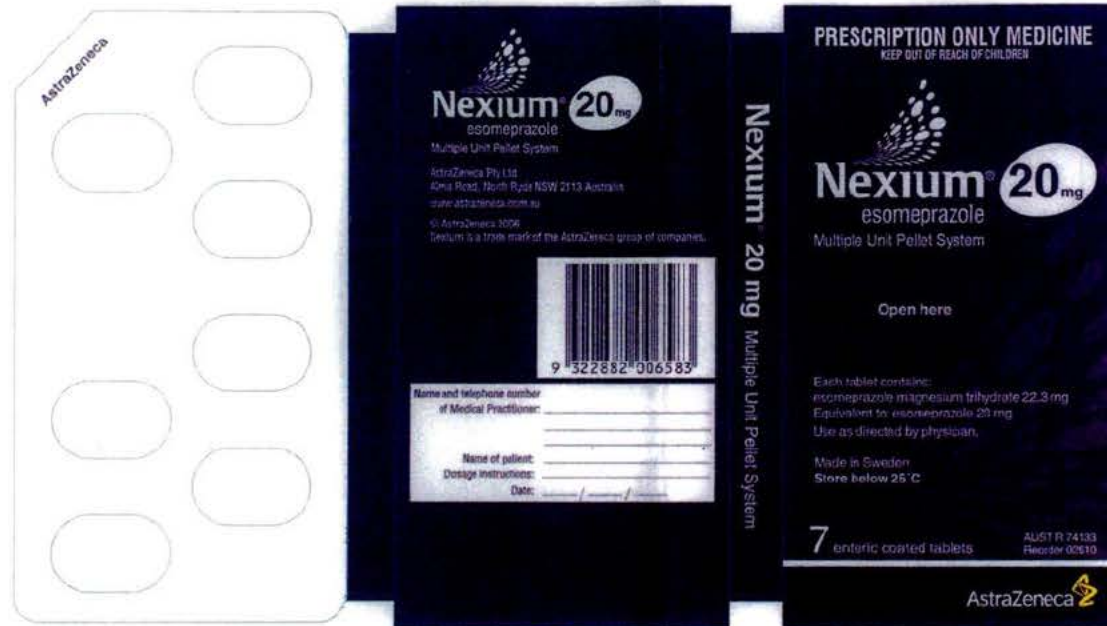


↑
Batch and Expiry
printed during
packaging

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Used Colours	Artwork made in Adobe Illustrator version: CS
PMS 269	Designed in accordance with the Packaging Manual <input type="checkbox"/>
PMS 130	If not, specify the reason: Regulatory: <input type="checkbox"/> OTC: <input type="checkbox"/>
PMS 2607	Other: ...
PMS 370	Braille:
PMS	Line 1:
	Line 2:

Department	Signature	Date
Regulatory s22	s22	25/09/06
Marketing s22		25/9/06
Medical s22		25/9/06
Other		
Date sub:		Date approved:

Existing labels



Batch and Expiry
Printed during
Packaging

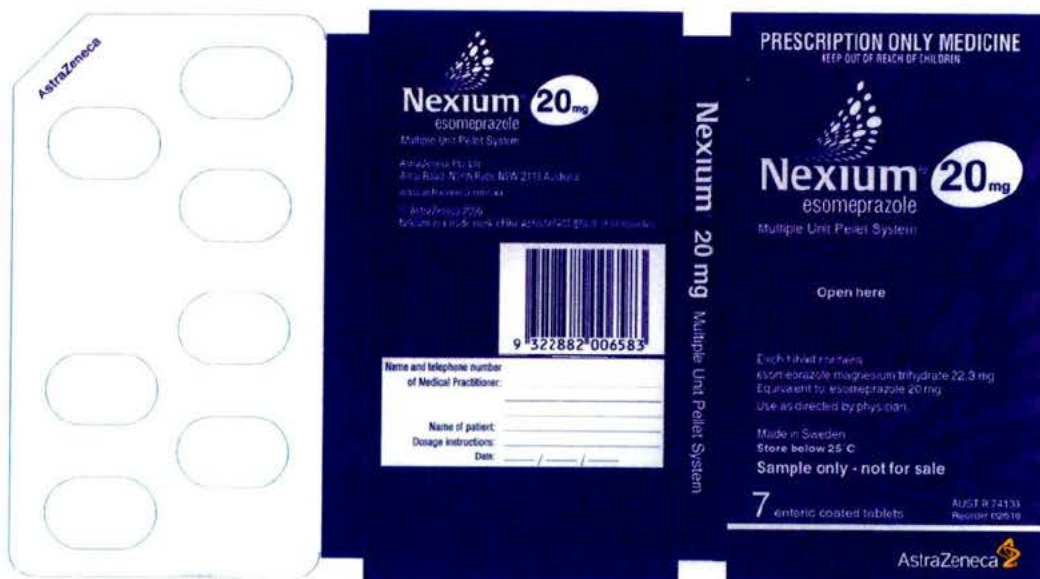
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PMS 130	If not, specify the reason: Regulatory: <input type="checkbox"/> OTC: <input type="checkbox"/>
PMS 2607	Other: ...
PMS	Braille:
PMS	Line 1:
	Line 2:

Department	Signature	Date
Regulatory s22	s22	25/09/06
Marketing s22		25/9/06
Medical s22		25/9/06
Other		
Date submitted:		Date approved:

FOI 26-2841 - Document 24
Physicians Sample

Department	Signature	Date
Regulatory	s22	27/05/08
Marketing		28/5/08
Medical		29/5/08
Other		28/5/08
Date approved:		

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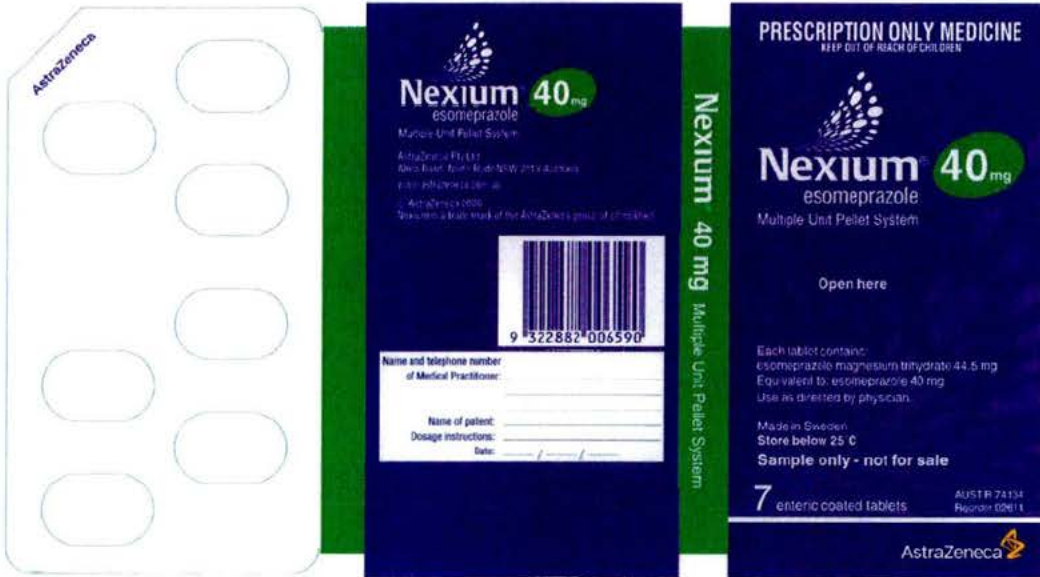


Batch and Expiry
printed during packaging

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PMS 130	PMS	Created by s22
PMS 2607	PMS	Latest revised by:
Black	PMS	AstraZeneca Sweden Operations

Department	Signature	Date
Regulatory	s22	28/05/08
Marketing		28/5/08
Medical		28/5/08
Other		28/5/08
Date submitted:		Date approved:

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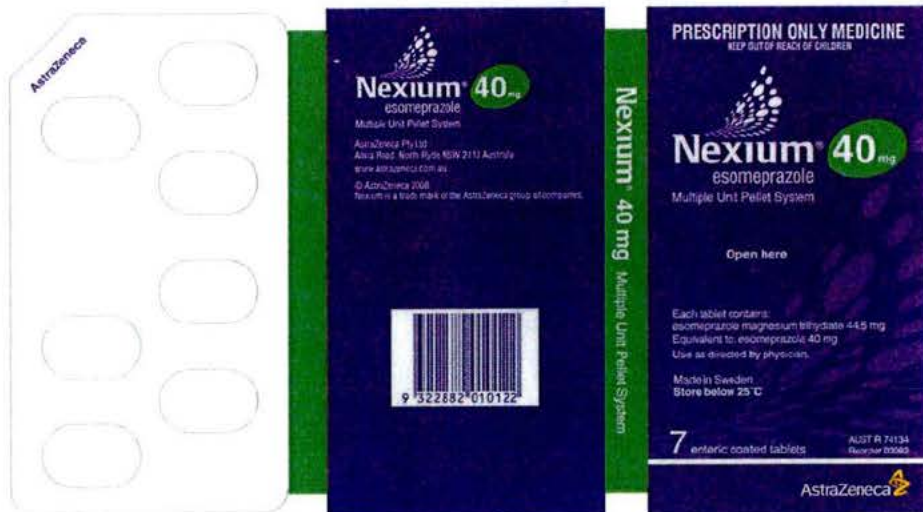


Batch and expiry ↑
printed during packaging

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PMS 130	PMS	Created by: s22
PMS 2607	PMS	Latest revised by:
Black	PMS	AstraZeneca Sweden Operators

Department	Signature	Date
Regulatory	s22	09/04/08
Marketing		09/04/08
Medical		
Other	s22	14/04/08
Date submitted:		Date approved:

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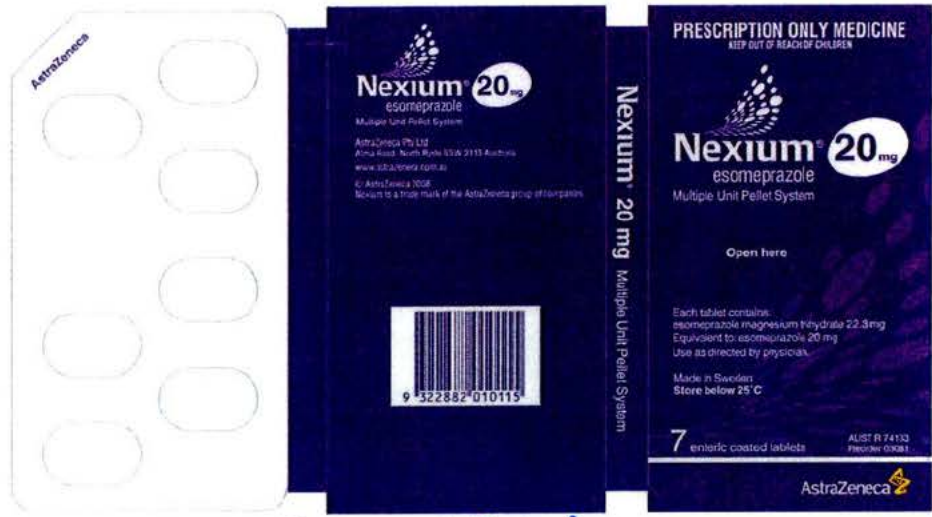


Batch and Expiry
Printed during packaging

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PMS 2607	PMS	
PMS 370	PMS	AstraZeneca Sweden Operations

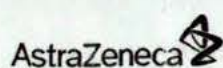
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Regulatory	s22	09/04/08
Marketing		09/04/08
Medical		
Other	s22	14/04/08
Date submit		Date approved:

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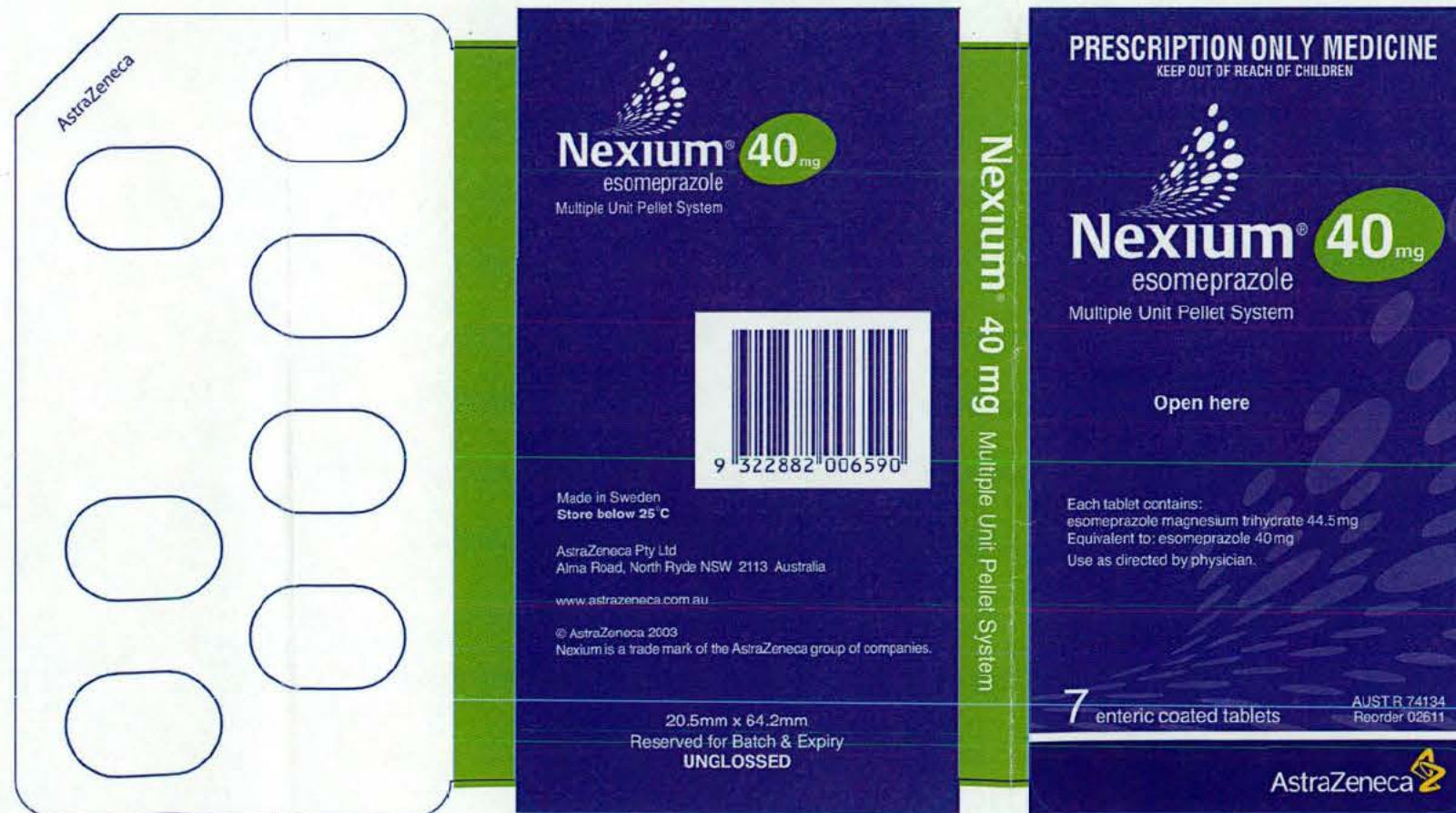
*Batch and Expiry ↑
printed during packaging*

PMS 269	PMS	Drawing: AZWA6009-B
PMS 130	PMS	Created by s22
PMS 2607	PMS	
PMS	PMS	AstraZeneca Sweden Operations

SIGNOFF AREA		
s22 Packaging Development Department Alma Road, North Ryde NSW 2113 Australia Ph: +61(0)2 9978 3500 Fax: +61(0)2 9978 3700 		
Approval Authority	Signed	Date
Technical		
Marketing		
Export		
Production		
Process Engineer		
On-line Test required:	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Regulatory		
TGA Approved for Release:		
TGA Conditions of using existing stock:		

ARTWORK INFORMATION				Colours used in Artwork	
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Machine:	N/A	Application:	Adobe Illustrator	<input type="checkbox"/> Gold 130C	
Comp. Type:	Wallet	Comp. Code:	0261101W	<input type="checkbox"/> Purple 2607C	
EAN code:	9322882006590	Art. / Part no.:	63 477 47	Dates of Revisions: Rev. 03 February 2004 03 October 2003	
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Country:	Domestic	Designed by:	AstraZeneca Australia		

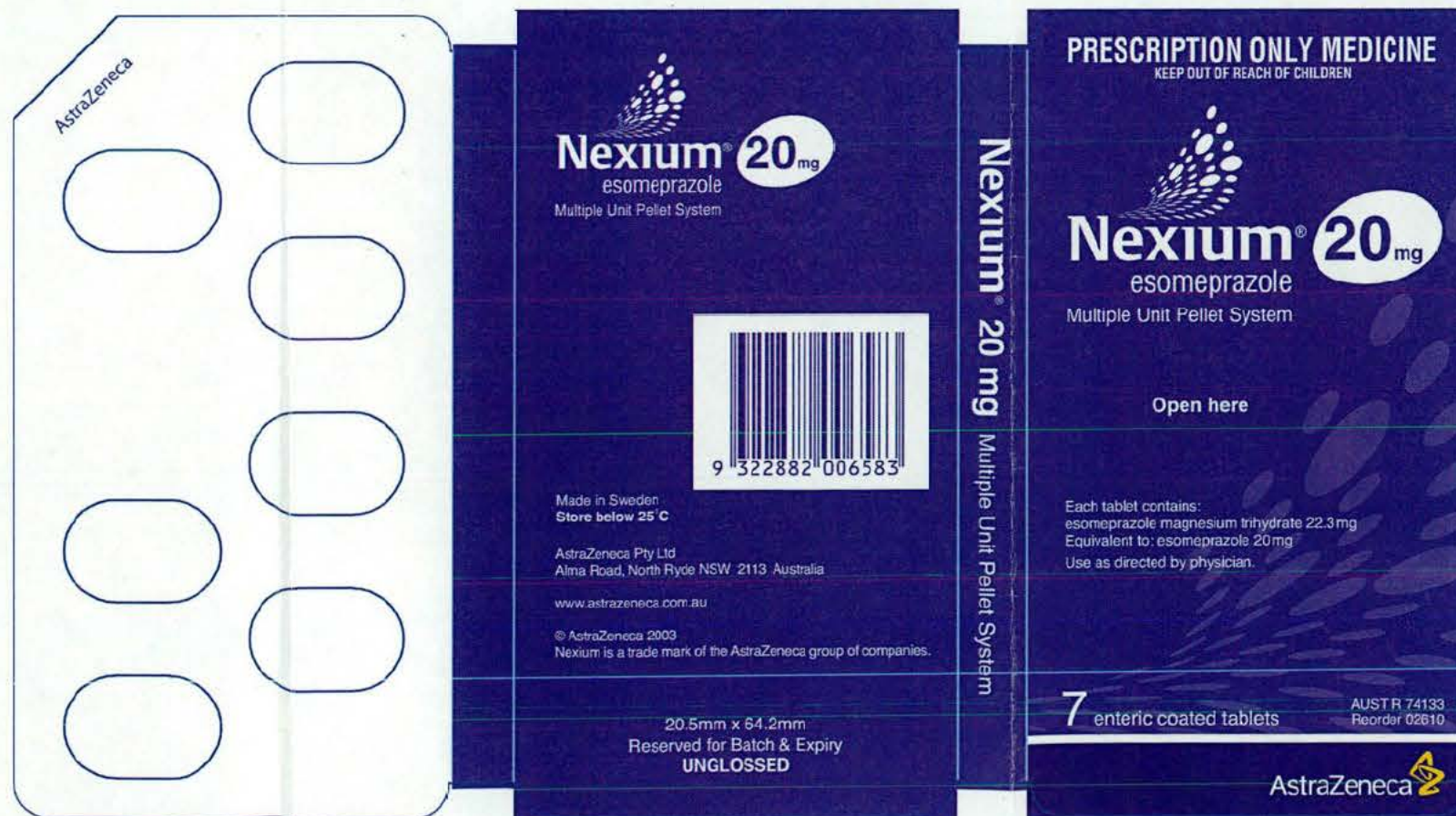
UNCONTROLLED COPY



SIGNOFF AREA		
s22 Packaging Development Department Alma Road, North Ryde NSW 2113 Australia Ph: +61(0)2 9978 3500 Fax: +61(0)2 9978 3700 		
Approval Authority	Signed	Date
Technical		
Marketing		
Export		
Production		
Process Engineer		
On-line Test required:	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Regulatory		
TGA Approved for Release:		
TGA Conditions of using existing stock:		

ARTWORK INFORMATION				Colours used in Artwork	
Dimensions:	116mm x 211.4mm			<input type="checkbox"/> Does not print	<input type="checkbox"/> Die Drawing - Does not print
Template:	A-3852. Edition A.	Platform:	Macintosh	<input checked="" type="checkbox"/> Purple 269C	
Machine:	N/A	Application:	Adobe Illustrator	<input checked="" type="checkbox"/> Gold 130C	
Comp. Type:	Wallet	Comp. Code:	0261002W	<input checked="" type="checkbox"/> Purple 2607C	
EAN code:	9322882006583	Art. / Part no.:	N/A	Dates of Revisions:	Rev. 03 February 2004 03 October 2003
Pharma Code:	PH 4485	Scale:	1:1	No. of Revision:	01
Country:	Domestic	Designed by:	AstraZeneca Australia		

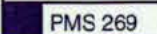
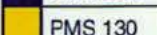

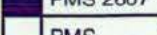
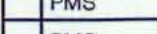
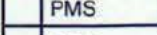
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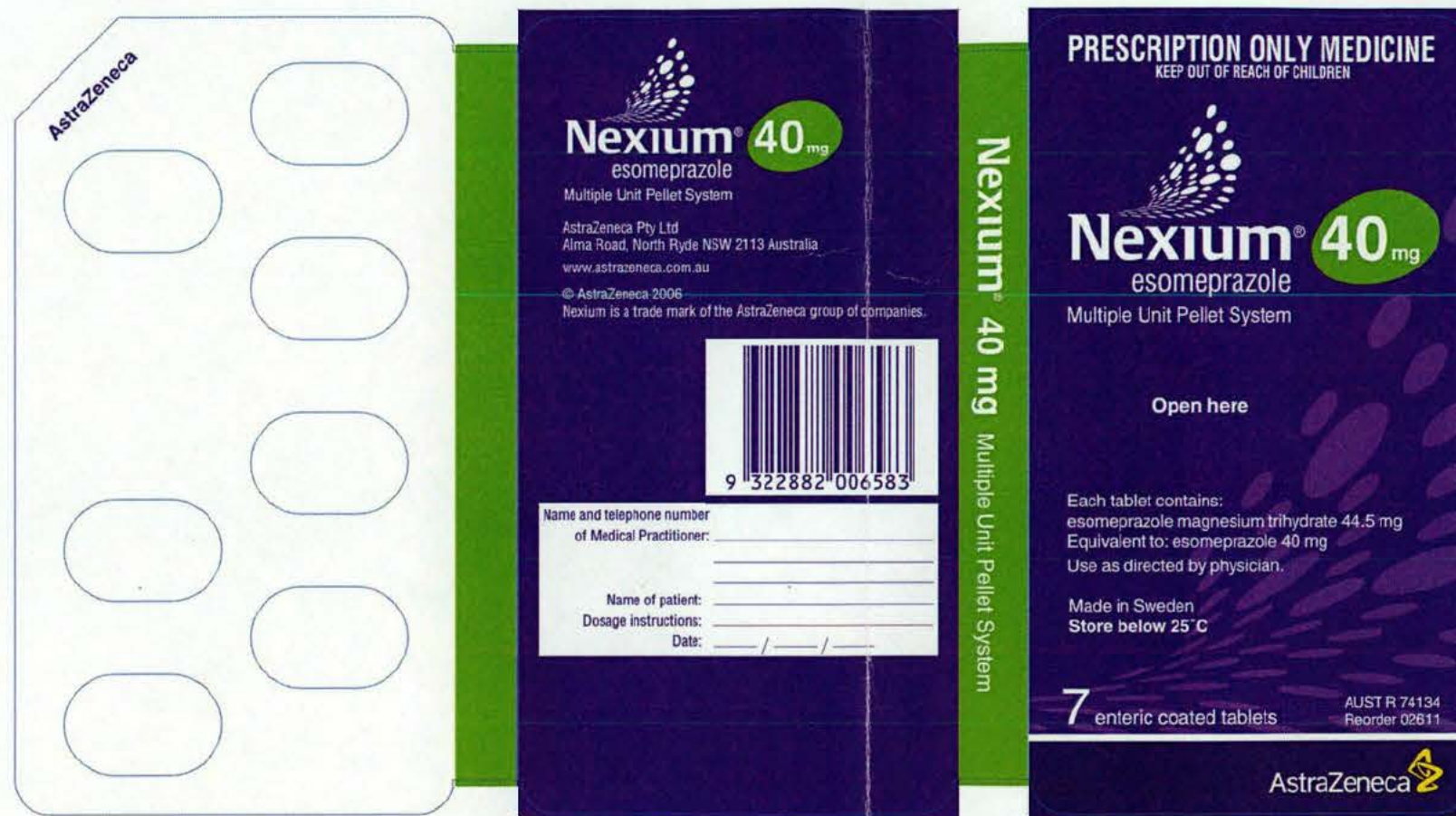
Proposed Labels



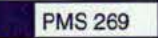
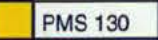
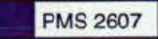
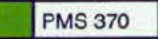
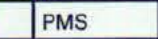
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Used Colours	Artwork made in Adobe Illustrator version: CS
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 PMS 130	If not, specify the reason: Regulatory: <input type="checkbox"/> OTC: <input type="checkbox"/>
 PMS 2607	Other: ...
 PMS	Braille:
 PMS	Line 1:
 PMS	Line 2:

Status	User Name	Date	Comment
Approved	s22	22/09/2006 7:43:10 PM	<p data-bbox="1276 1365 1721 1470"><i>[Faint handwritten text, possibly mirrored bleed-through from the reverse side of the page]</i></p>



↑ Batch No. and Expiry Date printed during manufacture

AstraZeneca Sweden Operations (Template made in Adobe Illustrator 8.0)	
Used Colours	Artwork made in Adobe Illustrator version: CS
 PMS 269	Designed in accordance with the Packaging Manual <input type="checkbox"/>
 PMS 130	If not, specify the reason: Regulatory: <input type="checkbox"/> OTC: <input type="checkbox"/>
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 PMS 370	Braille:
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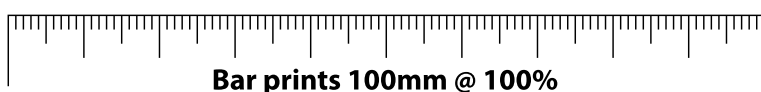


AstraZeneca	Schawk Job No.: 105331726/402324970 0010	Printable Colours:	Non Print:
	Date: 14-04-2021	Black	Cyan
	Ops Component Code: CN65-160A	Yellow	Magenta
	Drawing Ref: ISP-P-71027C	P695	P130
	Packing Code 1: 4535	P269	Technical Info
	Description: Losec MUPS Unit Carton-20mg-30T-AU		Profile

SGK is a Matthews International Corporation

TEXT AREA

Dimensions
74x35x105 mm



Bar prints 100mm @ 100%

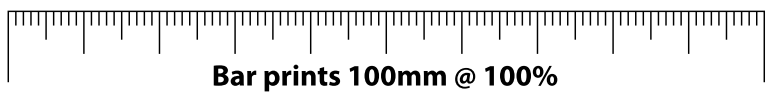
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	Ops Component Code: CN65-156C			
	Drawing Ref: ISP-P-71027C			
	Packing Code 1: 3906			
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Description: Losec MUPS Unit carton 10mg-30T-AU				

TEXT AREA

Dimensions
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Bar prints 100mm @ 100%

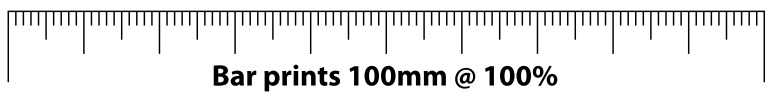
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Body text size	Smallest text size			
6.0 pt	6.0 pt			



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	Date:	28-11-2020						
	Ops Component Code:	CN65-158C						
	Drawing Ref:	ISP-P-71027C						
	Packing Code 1:	3908						
	Packing Code 2:	N/A						
Description:	Losec MUPS Unit carton 20mg-30T-AU							

TEXT AREA

Dimensions
74x35x105 mm



SGK is a Matthews International Corporation	
Body text size	Smallest text size
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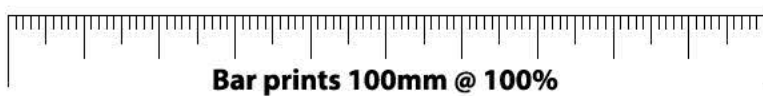
AstraZeneca Pharmaceutical Co., Ltd , No.2, Huangshan Rd, Wuxi, China Tel: + 86 510 85220000 Fax: + 86 510 85227777					
PM name:	Article No.	PHARM code:	Scale	Flutter Mark	Dimensions: (mm)
Unit Carton for Losec 20mg 30s(AU)	CN63-007	7342	100%	10,13	105x74x35
Designer /Date	s22	2012-07-05	Checker/ Date		
Approval Authority Signed			Colours used in Artwork		
Legal Affairs:	Date:		Does not print	Unglossed	
Regulatory Affairs:	Date:		PMS695C	PMS269C	
Marketing:	Date:		PMS130C	Cyan	
			Magenta	Yellow	
			BlackC		
			Edition	Revised date	
			A	2012-07-05	





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	Date: 14-08-17			
	Ops Component Code: CN65-155E			
	Drawing Ref: ISP-P-71027C			
	Packing Code: 4535			
	Description: Losec MUPS 10mg-30T UnitCarton Australia			
Created By: AH				

TEXT AREA



Bar prints 100mm @ 100%

Body text size	Smallest text size
6.0 pt	6.0 pt

Annotations

ID	Page	Date	First Name	Last Name	Content
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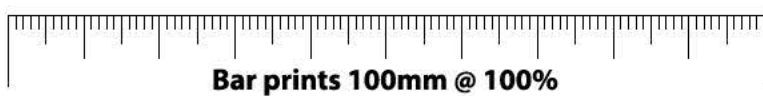
Approvals

Date	First Name	Last Name	Type
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16-Aug-17 15:03:17	s22	s22	approved
16-Aug-17 15:41:31	s22	s22	approved
18-Aug-17 17:53:17	s22	s22	approved



	Schawk Job No.: 480778-A07	Printable Colours: Black Cyan Magenta Yellow P695 P130 P269	Non Print: Technical Info Profile	SCHAWKI
	Date: 02-09-17			
	Ops Component Code: CN65-157F			
	Drawing Ref: ISP-P-71027C			
	Packing Code: 4536			
	Description: Losec MUPS 20mg UnitCarton Australia			
Created By: PR				

TEXT AREA



Body text size	Smallest text size
6.0 pt	6.0 pt

Annotations

ID	Page	Date	First Name	Last Name	Content
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Approvals

Date	First Name	Last Name	Type
04-Sep-17 12:03:10	s22	s22	approved
05-Sep-17 09:04:40	s22	s22	approved

AstraZeneca Pharmaceutical Co., Ltd., No.2, Huangshan Rd, Wuxi, China Tel: + 86 510 85220000 Fax: + 86 510 85227777					
PM name:	Article No.	PHARM code:	Scale	Flutter Mark	Dimensions: (mm)
Unit Carton for Losec 10mg 30s(AU)	CN63-005	7340	100%	12,37	105x74x35
Designer /Date	s22 /2012-07-05		Checker/ Date		
Approval Authority Signed			Colours used in Artwork		
Legal Affairs:	Date:		Does not print	Unglossed	
Regulatory Affairs:	Date:		PMS109C	PMS269C	
Marketing:	Date:		PMS130C	Cyan	
			Magenta	Yellow	
			BlackC		
			Edition	Revised date	
			A	2012-07-05	



Proposed

AstraZeneca Pharmaceutical Co., Ltd., No.2, Huangshan Rd, Wuxi, China Tel: + 86 510 85220000 Fax: + 86 510 85227777					
PM name:	Article No.	PHARM code:	Scale	Flutter Mark	Dimensions: (mm)
Unit Carton for Losec 20mg 30s(AU)	CN63-007	7342	100%	10,13	105x74x35
Designer /Date	s22 /2012-07-05			Checker/ Date	
Approval Authority Signed				Colours used in Artwork	
Legal Affairs:	Date:			Does not print	Unglossed
Regulatory Affairs:	Date:			PMS695C	PMS269C
Marketing:	Date:			PMS130C	Cyan
				Magenta	Yellow
				BlackC	
				Edition	Revised date
				A	2012-07-05



Proposed

s22

Marketing:

Date:

24/09/10

Edition

Revised date

FOI 26-2841 - Document 36

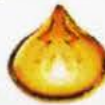
95

PRESCRIPTION ONLY MEDICINE
KEEP OUT OF REACH OF CHILDREN

LOSEC® Tablets

Multiple Unit Pellet System **10 mg**

Each tablet contains:
Omeprazole magnesium ... 10.3 mg
Equivalent to:
Omeprazole 10 mg
Use as directed by physician



30 enteric coated tablets

AUST R 63414
Reorder 03178

LOT 12345678
EXP MM-YYYY



AstraZeneca

LOSEC® Tablets

Multiple Unit Pellet System **10 mg**

AstraZeneca

CN63-434C
6425



9 522882 005029 6

Please place pharmacy label here

LOSEC® Tablets

Multiple Unit Pellet System **10 mg**



Please ask your pharmacist for information about this medicine.
Consumer medicine information is also available at
www.astrazeneca.com.au/CMi

Made in Sweden
Store below 25°C
AstraZeneca Pty Ltd
Alma Road, North Ryde NSW 2113 Australia
www.astrazeneca.com.au

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This carton is RECYCLABLE.



LOSEC® Tablets
Multiple Unit Pellet System **10 mg**

AstraZeneca

PRESCRIPTION ONLY MEDICINE
KEEP OUT OF REACH OF CHILDREN

Losec® Tablets
Multiple Unit Pellet System **20 mg**

Each tablet contains:
Omeprazole magnesium ... 20.6 mg
Equivalent to:
Omeprazole 20 mg
Use as directed by physician



30 enteric coated tablets

AUST R 63416
Reorder 03180



LOT 12345678
EXP MM-YYYY



Losec® Tablets
Multiple Unit Pellet System **20 mg**



CNS-196C
6427



Please place pharmacy label here

Losec® Tablets
Multiple Unit Pellet System **20 mg**



Losec® Tablets
Multiple Unit Pellet System **20 mg**

Please ask your pharmacist for information about this medicine
Consumer medicine information is also available at
www.astrazeneca.com.au/CM

Made in Sweden
Store below 25°C
AstraZeneca Pty Ltd
Alma Road, North Ryde NSW 2113, Australia
www.astrazeneca.com.au

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Prescription direction



Department	Signature
Regulatory	
Marketing	
Medical	
Other	