

OXYNORM[®] Capsules

Oxycodone hydrochloride (ox-ee-code-own hi-dro-klor-ide)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about OXYNORM capsules.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine 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 OXYNORM capsules are taken for

OXYNORM capsules contain oxycodone hydrochloride.

Oxycodone belongs to a group of medicines called opioid analgesics.

OXYNORM capsules are used to relieve moderate to severe pain.

Opioid analgesics such as oxycodone hydrochloride have been used to treat pain for many years.

Your doctor, however, may prescribe it for another purpose.

Ask your doctor if you have any questions about why it has been prescribed for you.

As with all strong painkillers, your body may become used to you taking OXYNORM capsules. Taking it may result in physical dependence.

Physical dependence means that you may experience withdrawal symptoms if you stop taking oxycodone suddenly, so it is important to take it exactly as directed by your doctor.

This medicine is only available with a doctor's prescription.

Before you take it

When you must not take it

Do not take OXYNORM capsules if you:

- suffer from shallow breathing or have any breathing problems such as acute asthma, chronic bronchitis or impaired lung function
- are severely drowsy or have a reduced level of consciousness
- suffer from irregular or fast heartbeats or changes in the way the heart beats
- have heart problems or heart disease including if due to long-term lung disease
- have just drunk a large amount of alcohol, regularly drink large amounts of alcohol or have confusion and shaking due to stopping drinking alcohol
- suffer from convulsions, fits or seizures
- have a head injury, brain tumour or have increased pressure in your head or spine
- have severe abdominal pain with bloating, cramps, vomiting or constipation

- have a condition where your stomach empties more slowly than it should, your small bowel does not work properly or you have just had an operation on your abdomen
- are about to have an operation including surgery on your spine for pain relief in the next 6 hours
- have severe kidney or liver disease
- take medicine for depression called a 'monoamine oxidase inhibitor' or have taken any in the last two weeks.

Do not take OXYNORM capsules if you are allergic to oxycodone, opioid painkillers, or any of the ingredients listed at the end of this leaflet.

Do not take this medicine after the expiry date (EXP) printed on the pack.

If you take it after the expiry date has passed, it may not work very well.

Do not take it if the packaging is torn or shows signs of tampering.

Do not take this medicine if you are pregnant or intend to become pregnant whilst taking this medicine.

Like most medicines of this kind, OXYNORM capsules are not recommended to be taken during pregnancy. Your doctor will discuss the risks and benefits of taking them if you are pregnant.

Do not give this medicine to a child younger than 18 years of age.

Safety and effectiveness in children younger than 18 years of age has not been established.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any medical conditions, especially the following:

- low blood pressure including from having low blood volume
- increased prostate size or difficulty passing urine
- chronic lung, liver or kidney disease
- problems or recent surgery of your gall bladder or bile duct
- inflammation of the pancreas
- adrenal glands not working properly
- underactive thyroid gland
- inflammatory bowel disease or recent abdominal surgery
- severe mental condition involving losing contact with reality, hearing voices or an inability to think clearly
- an addiction or history of abuse of alcohol, opioids or other drugs.

This medicine is not recommended to be taken during labour.

Oxycodone given to the mother during labour can cause breathing problems in the newborn.

Tell your doctor if you are breast feeding or planning to breast-feed.

Oxycodone can pass into the breast milk and can affect the baby. Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you take any OXYNORM capsules.

Taking other medicines

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 and OXYNORM capsules may interfere with each other. These include:

- medicines to treat depression, psychiatric or mental disorders. Medicines to treat depression belonging to a group called monoamine oxidase inhibitors must be stopped 14 days before OXYNORM capsules are taken.
- medicines to help you sleep
- medicines to put you to sleep during an operation or procedure
- medicines to relax your muscles
- medicines to lower blood pressure
- quinidine and other medicines to treat the heart
- medicines to thin the blood e.g. coumarin derivatives such as warfarin
- cimetidine, a medicine to treat ulcers
- medicines to relieve stomach cramps or spasms, to prevent travel sickness, to treat Parkinson's disease or to treat urinary incontinence
- medicines to stop nausea or vomiting e.g. metoclopramide
- other pain relievers including other opioids
- ketoconazole, a medicine to treat fungal infections
- alcohol.

These medicines or alcohol may be affected by OXYNORM capsules, may affect how well OXYNORM capsules work or may increase side effects. You may need to use different amounts of your medicines, or take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking this medicine.

How to take OXYNORM capsules

How much to take

Your doctor will tell you exactly how much to take.

Follow the instructions given to you by your doctor or pharmacist exactly.

How to take it

Swallow OXYNORM capsules whole with a full glass of water or other fluid.

Do not open, chew or crush them.

OXYNORM capsules are only designed to work properly if swallowed whole.

You must only take OXYNORM capsules by mouth.

Taking this medicine in a manner other than that prescribed by your doctor can be harmful to your health.

If you have trouble swallowing your capsules whole, talk to your doctor.

When to take it

Take OXYNORM capsules every 4 to 6 hours or as directed by your doctor.

If you begin to experience pain and you are taking your OXYNORM capsules as prescribed, contact your doctor as your dosage may have to be reviewed.

Do not take two doses within 4 hours of each other.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

If you stop taking this medicine suddenly, your pain may worsen and you may experience withdrawal symptoms such as:

- body aches
- loss of appetite, nausea, stomach cramps or diarrhoea
- fast heart rate
- sneezing or runny nose

- chills, tremors, shivering or fever
- trouble sleeping
- increased sweating and yawning
- weakness
- nervousness or restlessness.

If you need to stop taking this medicine, your doctor will gradually reduce the amount you take each day, if possible, before stopping the medicine completely.

If you forget to take it

If you forget to take your capsules, take your next dose as soon as you remember, unless it is almost time for your next dose, then go on as before.

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

This will increase the chance of you getting unwanted side effects.

If you are not sure what to do, ask your doctor or pharmacist.

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too many OXYNORM capsules.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Keep telephone numbers for these places handy.

If someone takes an overdose they may experience difficulties in breathing, become drowsy and tired, lack muscle tone, have cold or clammy skin, have constricted pupils, have very low blood pressure or slow heart rate, and possibly may even become unconscious or die.

When seeking medical attention, take this leaflet and any remaining capsules with you to show the doctor. Also tell them about any other

medicines or alcohol which have been taken.

While you are taking it

Things you must do

Take OXYNORM capsules exactly as your doctor has prescribed.

Before you start on a new medicine, remind your doctor and pharmacist that you are taking OXYNORM capsules.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

Tell your doctor if your pain is getting worse. Always discuss any problems or difficulties you have while you are taking OXYNORM capsules.

Tolerance to oxycodone may develop which means that the effect of the medicine may decrease. If this happens, your doctor may increase the dose so that you get adequate pain relief.

Keep enough OXYNORM capsules with you to last over weekends and holidays.

Things you must not do

Do not drink alcohol while you are taking OXYNORM capsules.

Alcohol use could increase serious side-effects of oxycodone, such as sleepiness and drowsiness, and slow and shallow breathing.

Do not take OXYNORM capsules to treat any other complaint 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, exceed the dose recommended or change the dosage without checking with your doctor.

Over time your body may become used to you taking oxycodone so if you stop taking it suddenly, your pain may worsen and you may have unwanted side effects such as withdrawal symptoms. This is called physical dependence.

If you need to stop taking this medicine, your doctor will gradually reduce the amount you take each day, if possible, before stopping the medicine completely.

Things to be careful of

Do not drive or operate machinery until you know how OXYNORM capsules affects you.

OXYNORM capsules may cause drowsiness, dizziness, hallucinations, disorientation, blurred vision or other vision problems or may affect alertness. Discuss these aspects and any impact on your driving or operating machinery with your doctor.

Be careful if you are elderly, unwell or taking other medicines.

Some people may experience side effects such as drowsiness, confusion, dizziness and unsteadiness, which may increase the risk of a fall.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Tell your doctor if you suffer from nausea or vomiting when taking OXYNORM capsules.

If you vomit after your dose, your pain may come back, as you may not have absorbed your medicine. If this happens, speak to your doctor. Your doctor may prescribe some medicine to help you stop vomiting.

Tell your doctor if taking OXYNORM capsules causes constipation.

Your doctor can advise you about your diet, the proper use of laxatives and suitable exercise you can do to help you manage this.

There is potential for abuse of oxycodone and the development of addiction to oxycodone. It is important that you discuss this issue with your doctor.

Side effects

All medicines may have some unwanted side effects. Sometimes they are serious but most of the time they are not. As for many other medicines of this type, that is opioid analgesics, many side effects tend to reduce over time, with the exception of constipation. This means that the longer you take this medicine, the less it may cause problems for you. Your doctor has weighed the risks of this medicine against the benefits they expect it will have for you.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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

This medicine helps most people with moderate to severe pain, but it may have unwanted side effects in a few people. Other side effects not listed here may also occur in some people.

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:

- mild abdominal symptoms such as diarrhoea, feeling sick, loss of appetite or constipation
- dry mouth, hiccups, sore throat, trouble swallowing or changes in voice
- sweating
- feeling anxious or nervous, trouble sleeping or abnormal dreams
- trouble with your balance
- new problems with your eyesight
- skin rash, itching, chills or fever
- muscle twitching
- swelling of legs or ankles.

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

- stomach discomfort, vomiting, indigestion or abdominal pain
- abnormal thinking, changes in mood or feeling deep sadness
- drowsiness, fainting or dizziness especially when standing up
- slow or noticeable heartbeats
- headache or confusion
- unusual weakness or loss of strength
- changes in passing urine such as the volume passed, pain or feeling the need to urinate urgently.

The above list includes serious side effects that may require medical treatment.

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

- you have an allergic reaction: shortness of breath, wheezing, shallow or difficult breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin
- seizures, fits or convulsions
- fast or irregular heartbeats

- chest pain or chest tightness.

The above list includes very serious side effects. You may need urgent medical attention or hospitalization.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

When seeking medical attention, take this leaflet and any remaining capsules with you to show the doctor.

After taking it

Storage

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

If you take the capsules out of the blister pack they may not keep as well.

Keep your capsules in a cool, dry place, where the temperature stays below 30°C.

Do not store it or any other medicine in the bathroom, near a sink or on a window sill.

Do not leave it in the car on hot days.

Heat and damp can destroy some medicines.

Keep it where 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 the capsules or the capsules have passed their expiry date, ask your pharmacist how to dispose of medicines no longer required.

Product description

What it looks like

OXYNORM® capsules come in three strengths:

5 mg - orange and beige, printed with "ONR 5"

10 mg - white and beige, printed with "ONR 10"

20 mg - pink and beige, printed with "ONR 20".

OXYNORM® capsules come in boxes containing blister packs of 20 capsules.

Ingredients

Active ingredients:

- 5 mg capsules contain 5 mg oxycodone hydrochloride
- 10 mg capsules contain 10 mg oxycodone hydrochloride
- 20 mg capsules contain 20 mg oxycodone hydrochloride

Inactive ingredients:

- microcrystalline cellulose
- magnesium stearate
- sodium lauryl sulfate
- gelatin
- black ink containing shellac, iron oxide black, propylene glycol.

In addition, the capsules also contain the colourants listed below:

5 mg - E110 (sunset yellow), E132 (indigo carmine), E171 (titanium dioxide), E172 (iron oxide red and yellow)

10 mg & 20 mg - E132 (indigo carmine), E171 (titanium dioxide), E172 (iron oxide red and yellow).

This medicine does not contain lactose, sucrose, gluten or tartrazine.

Manufacturer / Sponsor

OXYNORM® capsules are made in the UK and supplied in Australia by:

Mundipharma Pty Limited

ABN 87 081 322 509

50 Bridge Street

Sydney, NSW, 2000

Phone: 1800 188 009

®: OXYNORM is a registered trademark.

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Australian Registration Numbers for OXYNORM® Capsules:

5 mg: AUST R 74145

10 mg: AUST R 74143

20 mg: AUST R 74141