

OXYNORM[®] Liquid

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 liquid.

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 liquid is taken for

OXYNORM liquid contains oxycodone hydrochloride.

Oxycodone belongs to a group of medicines called opioid analgesics.

OXYNORM liquid is used to relieve moderate to severe pain.

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 liquid. 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

Long-term use of OXYNORM liquid may result in a decrease in sex hormone levels which may affect sperm production in men and the menstrual cycle in females. Talk to your doctor if you have any concerns.

When you must not take it

Do not take OXYNORM liquid if you:

- have any breathing problems such as acute asthma, respiratory depression (breathing slows or weakens) or other obstructive airways disease
- 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 disease if due to long-term lung disease
- have just consumed a large amount of alcohol, regularly consume large amounts of alcohol or have confusion and shaking due to alcohol withdrawal
- suffer from convulsions, fits or seizures
- have a head injury, brain tumour or raised pressure within the head, brain or spinal cord

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

Do not take OXYNORM liquid 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 liquid is not recommended to be taken during pregnancy. Your doctor will discuss the risks of taking it 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 have 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
- increased prostate size or difficulty passing urine
- chronic lung, liver or kidney disease
- disease of your gall bladder or bile duct
- inflammation of the pancreas
- underactive adrenal glands
- 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 should not be taken while breastfeeding. Oxycodone can pass into the breast milk and can harm 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 OXYNORM liquid.

Taking other medicines

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

Some medicines, dietary supplements and OXYNORM liquid 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 liquid is 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 treat convulsions e.g. phenytoin, carbamazepine
- medicines to thin the blood e.g. coumarin derivatives such as warfarin
- cimetidine, a medicine to treat stomach ulcers or heartburn
- medicines to relieve stomach cramps or spasms, to prevent travel sickness or symptoms of allergies
- medicines to treat Parkinson's disease
- medicines to treat urinary incontinence
- medicines to stop nausea or vomiting e.g. metoclopramide
- other pain relievers including other opioids
- medicines to treat fungal infections e.g. ketoconazole
- antibiotics e.g. clarithromycin, rifampin
- ritonavir, medicine to treat HIV infection and AIDS
- alcohol
- St John's wort (a herbal preparation)
- grapefruit and grapefruit juice.

These medicines, dietary supplements or alcohol may be affected by OXYNORM liquid, may

affect how well OXYNORM liquid works 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 and dietary supplements to be careful with or avoid while taking this medicine.

How to take OXYNORM liquid

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

Measure the dose accurately with a medicine measure.

Using a medicine measure such as a measuring glass or syringe, will ensure that you get the correct dose. You can buy a medicine measure from your pharmacist. Wipe the neck of the bottle and the cap after use to assist with re-opening.

OXYNORM liquid can be taken with some water or other fluid.

Food may affect how much medicine you absorb.

Therefore, take OXYNORM liquid either with or without food, but take it the same way every time.

You must only take OXYNORM liquid by mouth.

OXYNORM liquid is only designed to work properly if taken by mouth. Taking this medicine in a manner other than that prescribed by your doctor can be harmful to your health.

When to take it

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

If you begin to experience pain and you are taking your OXYNORM liquid 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 forget to take it

If you forget to take OXYNORM liquid, contact your doctor or pharmacist for advice.

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 (Australia: telephone 13 11 26, New Zealand: telephone 0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much OXYNORM liquid.

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

You may need urgent medical attention.

You should also follow the above steps if someone other than you has accidentally taken the liquid that was prescribed for you.

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 liquid 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 liquid exactly as your doctor has prescribed.

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

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 liquid.

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

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

Things you must not do

Do not drink alcohol while you are taking this medicine.

Drinking alcohol whilst taking OXYNORM liquid may make you feel more sleepy and increase the risk of serious side effects, such as shallow breathing with the risk of stopping breathing and loss of consciousness.

Do not take OXYNORM liquid 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 oxycodone. 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 liquid affects you.

OXYNORM liquid may cause drowsiness, dizziness, hallucinations, disorientation, blurred vision or other vision problems or may affect alertness. If you are affected, you should not drive or operate

machinery. Discuss these effects 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 liquid.

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 liquid causes constipation.

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

Not everybody experiences them.

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

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 (nausea), decreased appetite or constipation
- dry mouth, hiccups, sore throat, trouble swallowing or changes in voice
- excessive sweating
- feeling anxious or nervous, trouble sleeping or abnormal dreams
- trouble with your balance, vertigo, feeling faint
- skin rash, itching
- chills or fever
- new problems with your eyesight
- muscle problems such as spasms, twitching or tremors
- swelling of legs or ankles
- absence of menstrual periods
- impotence
- decreased sexual drive.

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, hallucinations
- unusual weakness or loss of strength or trouble walking
- changes in passing urine such as the volume passed, pain or feeling the need to urinate urgently, difficulty passing urine

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:

- your breathing slows or weakens
- 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.

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

After taking it

Storage

Keep your OXYNORM liquid in the original container with the lid tightly fastened until it is time to take it.

If you take the mixture out of the bottle or leave the lid off it may not keep well.

Keep your medicine 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 this medicine or the expiry date has passed, ask your pharmacist how to dispose of medicines no longer required.

Product description

What it looks like

OXYNORM® liquid is a clear, colourless to straw-coloured solution available in a 250 mL bottle.

It is available in one strength of 5 mg in 5 mL.

Ingredients

Active ingredient:

1 mL of OXYNORM® liquid contains 1 mg of oxycodone hydrochloride.

Inactive ingredients:

- saccharin sodium
- citric acid monohydrate
- sodium citrate
- sodium benzoate (as preservative)
- hypromellose.

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

Manufacturer / Sponsor

OXYNORM® liquid is supplied in Australia by:

Mundipharma Pty Limited

ABN 87 081 322 509

50 Bridge Street

Sydney, NSW, 2000

Phone: 1800 188 009

OXYNORM® liquid is supplied in New Zealand on behalf of Mundipharma New Zealand Limited by:

Pharmaco (NZ) Ltd

PO BOX 4079

Auckland 1140

Phone: (09) 337-3336

Medical enquiries: 0800 773 310

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This leaflet was updated in May 2014. Please check with your pharmacist that this is the latest version of the leaflet available.

The Australian Registration Number for OXYNORM® Liquid is

AUST R 77464

Orbis RA-0057 May 2014