

OXYNORM®

solution for injection or infusion

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 solution for injection or infusion ("injection or infusion").

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 being given this medicine against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, talk to your doctor or pharmacist.

Keep this leaflet in a safe place.

You may need to read it again.

What OXYNORM injection or infusion is given for

OXYNORM solution for injection or infusion contains oxycodone hydrochloride. Oxycodone belongs to a group of medicines called opioid analgesics.

OXYNORM injection or infusion is given to relieve moderate to severe pain such as that following an operation. It can be given as a single injection or as an infusion into a vein or into the tissue under the skin.

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 having oxycodone. Being given it may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop having oxycodone suddenly, so it is important that you are given OXYNORM injection or infusion exactly as directed by your doctor.

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

Before you are given OXYNORM injection or infusion

When you must not have it

You should not be given OXYNORM injection or infusion if you:

- suffer from shallow breathing or have any breathing problem 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 or are anxious from drinking alcohol
- suffer anxiety from taking hypnotics, medicines that are given to help people sleep
- suffer from convulsions, fits or seizures
- have a head injury, brain tumour, increased pressure in the head or spine
- have severe or acute abdominal pain with bloating, cramps, vomiting or chronic 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
- have severe kidney disease
- have moderate to severe liver disease
- are about to have surgery on your spine for pain relief in the next 6 hours
- take medicine for depression called a 'monoamine oxidase inhibitor' or have taken any in the last two weeks.

You should not have OXYNORM injection or infusion if you are allergic to oxycodone, opioid painkillers, or any of the

ingredients listed at the end of this leaflet.

You should not continue to have OXYNORM infusion 50 mg in 1 mL if you have been given OXYNORM infusion 50 mg in 1 mL for more than 4 consecutive weeks.

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

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

Do not use this medicine if the packaging is torn or shows signs of tampering or if the injection shows any visible signs of deterioration.

You should not be given this medicine if you are pregnant or intend to become pregnant whilst being given this medicine.

Like most medicines of this kind, OXYNORM injection or infusion is not recommended to be given during pregnancy. Your doctor will discuss the risks and benefits of having it if you are pregnant.

You should not be given this medicine if you are 18 years of age or younger.

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

Before you start to have 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
- you have had recent abdominal surgery, you are about to have surgery or you have had surgery within the last 24 hours
- 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 used 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 the risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you have OXYNORM injection or infusion.

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 injection or infusion 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 injection or infusion is given
- 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
- erythromycin, a medicine to treat bacterial infections
- ketoconazole, a medicine to treat fungal infections
- alcohol.

These medicines may be affected by OXYNORM injection or infusion, may affect how well OXYNORM injection or infusion works or may increase side effects. You may need to use different amounts of the medicines, or take different medicines.

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

How OXYNORM injection or infusion is given

How much is given

Your doctor will decide the appropriate dose for you.

How it is given

A doctor or nurse will usually prepare and administer the injection or infusion.

OXYNORM injection or infusion 10 mg in 1 mL or 20 mg in 2 mL

can be given as a single injection or infusion into a vein. It can also be administered through a fine needle into the tissue under the skin.

OXYNORM infusion 50 mg in 1 mL can only be given as an infusion into a vein or an infusion into the tissue under the skin.

Your doctor will decide the most appropriate way to administer OXYNORM injection or infusion. Using this medicine in a manner other than that prescribed by your doctor can be harmful to your health.

When it is given

You should be given OXYNORM injection or infusion as directed by your doctor.

If you begin to experience pain, tell your doctor as your dosage may have to be reviewed.

How long it is given for

You should be given this medicine for as long as directed by your doctor.

You should not be given OXYNORM infusion 50 mg in 1 mL for more than 4 consecutive weeks.

If you stop having this medicine suddenly, the 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 are given 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 are not already in hospital, if you think you or anyone else may have been given too much OXYNORM injection or infusion.

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 is given 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, any remaining medicine or the empty ampoule if you still have it with you to show your doctor. Also tell them about any other medicines or alcohol which have been taken.

While you are given OXYNORM injection or infusion

Things you must do

Before you start on a new medicine, remind your doctor and pharmacist that you are being given OXYNORM injection or infusion.

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

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

It may affect other medicines used during surgery.

If you become pregnant while being given 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 being treated with OXYNORM injection or infusion.

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.

Things you must not do

Do not drink alcohol while you are being given this medicine.

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

Do not use OXYNORM injection or infusion to treat any other complaint unless your doctor tells you to.

Do not give the medicine to anyone else, even if they have the same condition as you.

OXYNORM injection or infusion is intended for use in one patient only.

Do not stop using the medicine, exceed the dose recommended or change the dosage without checking with your doctor.

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

If you need to stop having this medicine, your doctor will gradually reduce the amount 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 injection or infusion affects you.

OXYNORM injection or infusion 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 having OXYNORM injection or infusion.

Your doctor may prescribe some medicine to help you stop vomiting.

Tell your doctor if having OXYNORM injection or infusion 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.

Tell your doctor if you find that you cannot concentrate or that you feel more sleepy than normal when you are being treated with OXYNORM injection or infusion or when the dose is increased.

This feeling should wear off after a few days.

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 have 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 as soon as possible if you do not feel well while you are having OXYNORM injection or infusion.

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, constipation or excessive wind
- dry mouth, hiccups or trouble swallowing
- sweating
- feeling anxious or nervous or have trouble sleeping
- trouble with your balance
- looking pale or feeling excessively tired
- new problems with your eyesight
- skin rash, itching, chills or fever
- unusually reduced or slow body movements
- swelling of legs or ankles
- pain at the injection site.

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, confusion, disorientation, sleepiness or impaired consciousness
- 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 the 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.

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 medicine with you to show the doctor.

After having it

Storage

OXYNORM injection or infusion should be given immediately after

opening the ampoule. Once opened, any unused portion should be discarded.

If you are being given OXYNORM injection or infusion in hospital, unopened ampoules will be stored in the pharmacy or on the ward.

If you have some of this medicine at home, keep the unopened ampoules in a cool, dry place where the temperature stays below 25°C and protected from light.

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.

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

Product description

What it looks like

OXYNORM® solution for injection or infusion is available in glass ampoules containing a clear, colourless solution. It is available in two presentations:

10 mg in 1 mL

20 mg in 2 mL.

OXYNORM® solution for infusion is available in glass ampoules containing a clear, colourless solution. It is available in one presentation:

50 mg in 1 mL.

OXYNORM® solution for injection or infusion and OXYNORM®

solution for infusion are supplied in packs of 5 ampoules.

Ingredients

Active ingredient:

1 mL of OXYNORM® solution for injection or infusion 10 mg in 1 mL and 20 mg in 2 mL both contain 10 mg of oxycodone hydrochloride.

1 mL of OXYNORM® solution for infusion 50 mg in 1 mL contains 50 mg of oxycodone hydrochloride.

Inactive ingredients:

- citric acid monohydrate
- sodium citrate
- sodium chloride
- hydrochloric acid (dilute)
- sodium hydroxide
- water for injections.

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

Manufacturer / Sponsor

OXYNORM® solution for injection or infusion and OXYNORM® solution for infusion 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.

This leaflet was updated in July 2010.

Australian Registration Numbers for OXYNORM® solution for injection or infusion are:

10 mg / 1 mL: AUST R 106965

20 mg / 2 mL: AUST R 106966

The Australian Registration Number for OXYNORM® solution for infusion is:

50 mg / 1 mL: AUST R 152411