

OxyNorm(R) Injection

Oxycodone hydrochloride

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start using OxyNorm(R) Injection.

This leaflet answers some of the common questions about OxyNorm(R) Injection. 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 using OxyNorm(R) Injection against the benefits they expect it will have for you.

OxyNorm(R) Injection should be used as instructed, and the advice given in this leaflet followed.

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

Keep this leaflet with your medicine.

You may need to read it again.

What OxyNorm(R) Injection is used for

OxyNorm(R) Injection is used 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 the vein, or it can be administered into the tissue under the skin.

OxyNorm(R) Injection contains oxycodone hydrochloride.

Oxycodone hydrochloride belongs to a class of drugs known as opioid analgesics.

Opioid analgesics such as oxycodone hydrochloride have been used to treat pain for many years. In most cases addiction does not occur. However, over time your body becomes used to taking oxycodone hydrochloride, so if you suddenly stop taking oxycodone hydrochloride you may experience some symptoms of withdrawal. It is important to discuss this issue with your doctor.

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

Your doctor may have prescribed it for another reason.

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

Be careful driving or operating machinery until you know how OxyNorm(R) Injection affects you as it may make you sleepy.

Before you use OxyNorm(R) Injection

When you must not use it

Do not use OxyNorm(R) Injection if you have an allergy to:

- * oxycodone hydrochloride
- * any of the ingredients in OxyNorm(R) Injection which are listed under the heading "Ingredients" at the end of this leaflet.
- * any other medicines known as opioid analgesics, e.g. morphine or codeine

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; fainting or hay fever.

Do not use OxyNorm(R) Injection if you have, or have had, any of the following medical conditions:

- * severe breathing problems such as asthma, wheezing or shortness of breath
- * irregular or rapid heartbeats
- * heart disease
- * fits or convulsions
- * head injury or brain tumour
- * severe headaches
- * non-functioning small bowel or delayed stomach emptying
- * severe stomach pain
- * impaired consciousness
- * DTs [confusion and shaking due to stopping drinking alcohol]
- * a condition where you have high levels of carbon dioxide in your blood
- * severe kidney disease
- * moderate to severe liver disease
- * chronic constipation
- * pregnancy

Do not use OxyNorm(R) Injection:

- * If you are taking medicine for depression called monoamine oxidase inhibitor [MAOIs], or you have taken any in the last two weeks.
- * If you regularly drink large amounts of alcohol.

Do not use OxyNorm(R) Injection after the expiry date [EXP] printed on the pack.

If you use this medicine after the expiry date has passed, it may not work as well.

Do not use OxyNorm(R) Injection if the packaging is torn or shows any signs of tampering, or if the injection shows any visible signs of deterioration.

Before you start to use it

Tell your doctor if you have or have had any other medical conditions including:

- * stomach pains or constipation
- * kidney or liver disease
- * increased prostate size
- * narrowing of the urinary tract
- * bile-duct increase or inflammation of the pancreas
- * disorientation, hallucination or severe headaches
- * low activity of the adrenal gland [Addison's disease]
- * inflammatory bowel disease
- * under-active thyroid
- * low blood pressure or blood volume
- * severe mental condition involving loss of contact with reality and being unable to think and judge clearly

Tell your doctor if you are about to have surgery.

Tell your doctor if you are pregnant or plan to become pregnant.

Your doctor can discuss with you the possible risks and benefits of using OxyNorm(R) Injection during pregnancy.

Tell your doctor if you are breastfeeding or plan to breastfeed.

Your doctor will discuss the risks and benefits of being treated with OxyNorm(R) Injection when breastfeeding. OxyNorm(R) passes into breast milk and is generally not recommended while you are breastfeeding.

If you have not told your doctor about any of the above, tell

him/her before you use OxyNorm(R) Injection.

OxyNorm(R) Injection is not recommended for children under 18 years of age.

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 may interfere with the effects of OxyNorm(R) Injection. These include:

- * Medicines used to treat depression belonging to a group called monoamine oxidase inhibitors [MAOIs]. They should be stopped 14 days before OxyNorm(R) Injection is used.
- * Medicines to treat high blood pressure
- * Medicines that cause sleepiness or muscle relaxation like sleeping tablets, antidepressants or antipsychotics.
- * Other opioid pain relievers
- * Alcohol
- * Medicines to stop nausea or vomiting
- * General anaesthetics
- * Medicines used to thin the blood e.g. warfarin
- * Medicines used to relieve stomach cramps or spasms, treat Parkinson's disease or prevent travel sickness
- * Medicines used to relax the muscles

Alcohol may also interfere with the effects of OxyNorm(R) Injection.

OxyNorm(R) Injection may change how these medicines work, or they may change how well OxyNorm(R) Injection works. These medicines or alcohol may increase the side effects of OxyNorm(R) Injection. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor has more information on medicines to be careful with or to avoid while being treated with OxyNorm(R) Injection.

How to use OxyNorm(R) Injection

How much to use

A doctor or nurse will usually prepare and administer the injection for you. The dose of OxyNorm(R) Injection may be different for each person. Your doctor will decide the right dose for you.

The amount of OxyNorm(R) Injection needed to give good pain relief varies. The doctor will take into account your age, weight, level of pain and medical history when choosing your dose.

How to use it

OxyNorm(R) Injection can be given as a single injection or infusion into the vein. If given by patient-controlled analgesia [PCA], the dose is worked out according to your weight, and the doctor or nurse will set the frequency at which it can be given. The injection can also be administered through a fine needle into the tissue under the skin.

When to use it

Use this medicine as directed by your doctor.

If, however, you begin to experience pain, and you are being treated with OxyNorm(R) Injection as prescribed [breakthrough pain] contact your doctor, as your medication may have to be reviewed.

How long to use it

Continue using this medicine for as long as your doctor tells you.

Speak to your doctor before stopping OxyNorm(R) Injection. If your body has become used to it, you may get withdrawal symptoms when you stop the medicine suddenly.

If you forget to use it

If it is almost time for your next dose skip the dose you missed and take your next dose when you are meant to. Otherwise, use it as soon as you remember, and then go back to using your medicine as you would normally.

If you do miss a dose, do not 'double' your next dose to 'make up' for the dose that you missed. If you are concerned, contact your doctor or pharmacist for advice.

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

If you use too much [overdose]

Immediately telephone your doctor, or the Poisons Information Centre [telephone 131 126], or go to casualty at your nearest hospital, if you think you or anyone else may have used too much OxyNorm(R) Injection. Do this even if there are no signs of discomfort or poisoning. Also report any other medicines or alcohol which have been taken. You may need urgent medical attention. Keep telephone numbers for these places handy.

If someone uses too much OxyNorm(R) Injection, they will probably become drowsy, tired confused, have very low blood pressure, experience difficulties in breathing and possibly become unconscious.

While you are using OxyNorm(R) Injection

Things you must do

Visit your doctor regularly for a check-up, and always discuss any problems or difficulties during or after being treated with OxyNorm(R) Injection.

Tell your doctor if your pain is getting worse, or if you are having frequent breakthrough pain.

Tell all the doctors, dentists and pharmacists who are treating you that you are being treated with OxyNorm(R) Injection.

If you become pregnant while you are being treated with OxyNorm(R) Injection, tell your doctor immediately.

If you plan to have any type of surgery, tell your doctor or anaesthetist or dentist that you are being treated with OxyNorm(R) Injection.

Things you must not do

Do not drive or operate machinery until you know how OxyNorm(R) Injection affects you.

OxyNorm(R) Injection may cause drowsiness or dizziness in some people and therefore may affect alertness. Ask your doctor's advice about whether or not it will be safe for you to drive a car, operate any machinery while being treated with OxyNorm(R) Injection or anything else that may be dangerous if you are drowsy.

Do not use OxyNorm(R) Injection for a longer time than your doctor has prescribed.

Do not drink alcohol while being treated with OxyNorm(R) Injection.

Do not give OxyNorm(R) Injection to anyone else, even if they have, or you think they have, the same condition as you.

Do not use OxyNorm(R) Injection to treat other complaints unless your doctor tells you.

Do not stop being treated with OxyNorm(R) Injection, without checking with your doctor.

OxyNorm(R) Injection should be used strictly according to your doctor's instructions.

Things to be careful of

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.

You may suffer from nausea or vomiting when being treated with OxyNorm(R) Injection.

OxyNorm(R) Injection can cause constipation. You should speak to your doctor about your diet, and proper use of laxatives.

Side effects

Tell your doctor as soon as possible if you do not feel well while you are being treated with OxyNorm(R) Injection.

OxyNorm(R) Injection helps most people with moderate to severe pain, but it may have unwanted side effects in some people.

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.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor to answer any of the questions you may have.

The most common side effects are:

- * nausea and vomiting
- * itchiness

- * headache, dizziness, drowsiness, sleepiness and feeling of extreme happiness

Other less common side effects include:

- * constipation, loss of appetite, stomach pain, dry mouth and excessive gas in the stomach or bowel
- * difficulty in sleeping, impaired consciousness, unusually reduced or slow body movement, disorientation, spinning sensation, tiredness
- * difficulty passing urine
- * increased production of a hormone causing fluid retention
- * low blood pressure, fast heart beat and widening of the blood vessels
- * swelling
- * shortness of breath, hiccup and rapid or deep breathing
- * rash
- * abnormal vision
- * pain, unusual tiredness or weakness and allergic reaction or pain at injection site, pale skin

Tell your doctor if you notice any other effect, even if it is not on this list. Some people may get other side effects while being treated with OxyNorm(R) Injection.

Ask your doctor if you do not understand anything in this list.

Habit forming effects

Opioid analgesics such as OxyNorm(R) Injection have been used to treat pain for many years. In most cases addiction does not occur. However, over time your body becomes used to taking OxyNorm(R) Injection, so if you suddenly stop using OxyNorm(R) Injection, you may experience some symptoms of withdrawal.

It is important to discuss this issue with you doctor.

After using OxyNorm(R) Injection

Storage

Usually, you would not be expected to store this medicine yourself as it would be given to you by a doctor or nurse.

Keep the ampoules in a cool, dry place below 25 degrees C and protected from light.

Do not store OxyNorm(R) Injection 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.

The injection should be kept in a safe place 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 what to do with any medicine that is left over.

Product description

What it looks like

OxyNorm(R) Injection 10mg/mL is a clear, colourless solution and comes in ampoules containing either 1mL or 2mL. There are 5 ampoules in a box.

Ingredients

OxyNorm(R) Injection contains oxycodone hydrochloride as the active ingredient.

Each mL of OxyNorm(R) Injection contains 10mg of oxycodone hydrochloride.

The inactive ingredients in OxyNorm(R) Injection are: citric acid monohydrate, sodium citrate, sodium chloride, hydrochloric acid [dilute], sodium hydroxide and water for injections.

Identification

The Australian Registration numbers can be located on the front of the carton.

OxyNorm(R) 10mg/mL Injection
10mg in 1mL AUST R 106965
20mg in 2mL AUST R 106966

Supplier

Mundipharma Pty Limited
ABN 87 081 322 509
Level 26, 6 O'Connell Street
Sydney, NSW, 2000

This leaflet was prepared in September 2005

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