

OxyNorm(R) Liquid

Oxycodone hydrochloride

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start taking OxyNorm Liquid.

This leaflet answers some of the 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 OxyNorm Liquid against the benefits they expect it will have for you.

Use OxyNorm Liquid as instructed, and follow the advice given in this leaflet.

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

Keep this leaflet with your medicine.

You may need to read it again.

What OxyNorm Liquid is used for

OxyNorm Liquid is used to relieve moderate to severe pain when other forms of treatment have not been effective. It is a solution taken by mouth.

OxyNorm Liquid belongs to a class of drugs known as opioid analgesics.

Opioid analgesics such as OxyNorm Liquid 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 Liquid, so if you suddenly stop taking OxyNorm Liquid, you may experience some symptoms of withdrawal. It is important to discuss this issue with your doctor.

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

Be careful driving or operating machinery until you know how OxyNorm Liquid affects you.

Before you take OxyNorm Liquid

When you must not take it

1. If you have allergies to:

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

2. If you have or have had any of the following medical conditions:

- * severe breathing problems such as asthma
- * 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

- * depression
 - * 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
- 3. If you are taking medicine for depression called monoamine oxidase inhibitor, or you have taken any in the last two weeks.**
- 4. If you regularly drink large amounts of alcohol.**
- 5. If you are about to have an operation.**

Do not take OxyNorm Liquid after the expiry date (Exp. Date) printed on the pack.

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

Do not take OxyNorm Liquid if the packaging is torn or shows any signs of tampering, or if the liquid shows any visible signs of deterioration.

Before you start to take it

You must tell your doctor if:

- 1. 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, dizziness standing up or severe headaches

- * low activity of the adrenal gland (Addison's disease)
- * inflammatory bowel disease
- * under-active thyroid

2. You are pregnant or plan to become pregnant.

Your doctor will discuss the possible risks and benefits of taking OxyNorm Liquid during pregnancy.

3. You are breastfeeding or plan to breastfeed.

Your doctor will discuss the risks and benefits of taking OxyNorm Liquid when breastfeeding. OxyNorm Liquid 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 them before you take any OxyNorm Liquid.

OxyNorm Liquid 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 OxyNorm Liquid. These include:

- * medication for depression
- * medication to help you sleep
- * medication for allergy
- * pain relievers
- * medicines used to treat blood clots.
- * medicine used to help lower blood pressure

Alcohol may also interfere with OxyNorm Liquid.

These medicines or alcohol may increase the side effects of OxyNorm Liquid. Your doctor or pharmacist can tell you what to do if you are taking any of these.

Your doctor has more information on medicines to be careful with, or to avoid, while taking OxyNorm Liquid.

How to take OxyNorm Liquid

How much to take

The dose of OxyNorm Liquid may be different for each person. Your doctor will decide the right dose for you.

The amount of OxyNorm Liquid 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 take it

Accurately measure the dose of OxyNorm Liquid with a metric measuring glass or oral syringe.

These devices can be purchased from your pharmacy.

OxyNorm Liquid can be taken with some water or other fluid.

Eating food immediately before, or after, taking OxyNorm Liquid may change how quickly it works. If you have noticed this, take it at least an hour before eating.

When to take it

Take this medicine as directed by your doctor.

OxyNorm Liquid is usually taken every 4 to 6 hours.

Take OxyNorm Liquid at the times you have been told. If, however, you begin to experience pain, and you are taking your OxyNorm Liquid as prescribed (breakthrough pain) contact your doctor, as your dosage may have to be reviewed.

OxyNorm Liquid must be taken regularly to control the pain. Taking OxyNorm Liquid at regular time intervals means that the onset of pain is prevented.

Do not take any alcohol while you are being treated with OxyNorm Liquid.

How long to take it

Continue taking OxyNorm Liquid until you finish the pack or until your doctor recommends.

If you forget to take it

If you forget to take a dose, contact your doctor or pharmacist for advice.

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

An example is taking your medicine at the same time each day, such as 6 am, 10 am, 2 pm, 6 pm and 10 pm.

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 131 126), or go to the Emergency Department 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. 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 takes too much OxyNorm Liquid, they will probably become drowsy, tired, confused, have very low blood pressure, experience difficulties in breathing and possibly become unconscious.

While you are taking OxyNorm(R) Liquid

Things you must do

Take OxyNorm Liquid exactly as your doctor has prescribed.

Visit your doctor regularly for a check-up, and always discuss any problems or difficulties during or after taking OxyNorm Liquid.

Tell your doctor if your pain is getting worse, or if you are having frequent breakthrough pain. Keep enough OxyNorm Liquid with you to last over weekends and holidays.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking OxyNorm Liquid.

If you become pregnant while you are taking OxyNorm Liquid, tell your doctor.

If you plan to have any type of surgery, tell your doctor or anaesthetist or dentist that you are taking OxyNorm Liquid.

Things you must not do

Do not drive or operate machinery until you know how OxyNorm Liquid affects you.

OxyNorm Liquid 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 taking OxyNorm Liquid or anything else that may be dangerous if you are drowsy.

Make sure you know how you react to OxyNorm Liquid before you drive a car, operate machinery, or do anything else that could be dangerous if you are drowsy, dizzy or not alert.

Do not take OxyNorm Liquid for a longer time than your doctor has prescribed.

Do not take alcohol while being treated with OxyNorm Liquid.

Do not change your dose without first checking with your doctor.

Do not give OxyNorm Liquid to anyone else, even if they have, or you think they may have, the same condition as you.

Do not use OxyNorm Liquid to treat other complaints unless your doctor tells you to.

Do not stop taking OxyNorm Liquid or lower your dosage,

without first checking with your doctor.

OxyNorm Liquid should be taken strictly according to your doctor's instructions.

Things to be careful of

Be careful driving or operating machinery until you know how OxyNorm Liquid affects you.

You may feel drowsy when you begin to take OxyNorm Liquid. If you drink alcohol the drowsiness may be worse.

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 taking OxyNorm Liquid.

OxyNorm Liquid 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 taking OxyNorm Liquid.

OxyNorm Liquid 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.

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

The most common side effects are:

- * stomach problems, such as pain, nausea, constipation, diarrhoea and vomiting
- * dizziness, drowsiness, confusion,

- nervousness and weakness
- * abnormal thoughts and dreams
- * trouble sleeping
- * dizziness standing up
- * headache
- * twitching
- * sore throat
- * fever, chills
- * dry mouth
- * anorexia
- * difficulties in breathing, increased cough, wheezing or chest pain
- * sweating.

Other less common side effects include:

- * stomach pain and excessive gas in the stomach or bowel
- * difficulty in swallowing and sore mouth
- * dehydration, fluid retention and thirst
- * ringing of the ears
- * urination problems
- * skin trouble, such as rash, itching, dryness, peeling, lumps or hives
- * flushing of the face
- * loss of memory, depression, disorientation, faintness, agitation, mood changes, speech difficulties, hallucinations, unconsciousness, fits or convulsions and restlessness
- * changes in heart beat rate
- * low muscle strength, abnormal manner of walking, muscle rigidity, shaking
- * general feeling of being unwell, pain and neck pain
- * increase in appetite and changes in taste
- * impotence
- * pins and needles
- * vision abnormalities.
- * swelling of the face, arms and legs

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 taking OxyNorm Liquid.

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

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

Habit forming effects

Opioid analgesics such as OxyNorm Liquid 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 Liquid, so if you suddenly stop taking OxyNorm Liquid, you may experience some symptoms of withdrawal. It is important to discuss this issue with you doctor.

After using OxyNorm(R) Liquid

Storage

Keep OxyNorm Liquid in the original container, in a cool, dry place, away from direct sunlight where the temperature stays below 30 degrees C. Do not store any medicine in the bathroom or near a sink. Do not leave any medicines in the car on hot days.

Heat and dampness 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 OxyNorm Liquid, or if your OxyNorm Liquid has passed its expiry date, return the unused medicine to your pharmacist.

Product description

What it looks like

OxyNorm Liquid 5 mg/5mL is a clear, colourless or straw coloured solution and comes in bottles of 250mL.

Ingredients

OxyNorm Liquid contains oxycodone hydrochloride, as the active ingredient.

Each 5 mL of OxyNorm Liquid contains 5 mg of oxycodone hydrochloride, which means that each mL of OxyNorm liquid contains 1 mg of oxycodone hydrochloride.

The inactive ingredients in OxyNorm Liquid are: saccharin sodium, citric acid monohydrate, sodium citrate, sodium benzoate (a preservative) and hypromellose.

Identification

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

OxyNorm Liquid 5 mg/5mL - AUST R 77464

Supplier

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

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