

OxyNorm(R) Capsules

Oxycodone hydrochloride

Consumer Medicine Information

What is in this leaflet

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

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

Use OxyNorm capsules 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(R) capsules are used for

OxyNorm capsules are used to relieve moderate to severe pain when other forms of treatment have not been effective.

OxyNorm capsules belong to a class of drugs known as opioid analgesics.

Opioid analgesics such as OxyNorm capsules 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 capsules, so if you suddenly stop taking OxyNorm capsules, 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 capsules affect you.

Before you take OxyNorm(R) capsules

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 capsules 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 capsules after the expiry date (exp) 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 capsules if the packaging is torn or shows any signs of tampering, or if the capsules show 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 capsules during pregnancy.

3. You are breastfeeding or plan to breastfeed.

Your doctor will discuss the risks and benefits of taking OxyNorm capsules when breastfeeding. The active ingredient from OxyNorm capsules 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 capsules.

OxyNorm capsules are 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 capsules. These include:

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

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

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

How to take OxyNorm(R) capsules

How much to take

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

The amount of OxyNorm capsules 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

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

Do not open, chew or crush OxyNorm capsules.

When to take it

Take this medicine as directed by your doctor.

OxyNorm capsules should be taken at 4 to 6 hourly intervals.

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

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

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

How long to take it

Continue taking OxyNorm capsules 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 many OxyNorm capsules. 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 many capsules, 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) capsules

Things you must do

Take OxyNorm capsules 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 capsules.

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

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

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

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

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

Things you must not do

Do not drive or operate machinery until you know how OxyNorm capsules affect you.

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

Make sure you know how you react to OxyNorm capsules 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 capsules for a longer time than your doctor has prescribed.

Do not take alcohol while being treated with OxyNorm capsules.

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

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

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

Do not stop taking OxyNorm capsules or lower your dosage, without first checking with your doctor.

OxyNorm capsules 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 capsules affect you.

You may feel drowsy when you begin to take OxyNorm capsules. 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 capsules. If you vomit two to three hours after your dose, your pain may come back, as you will not have absorbed your medicine. If this happens, speak to your doctor. Your doctor may prescribe some medicine to help you stop vomiting.

OxyNorm capsules 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 capsules.

OxyNorm capsules help 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 capsules.**

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

After using OxyNorm(R) capsules

Storage

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

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

OxyNorm capsules should be kept in a cool, dry place, where the temperature stays below 30 degrees C. Do not store it or any other medicine in the bathroom or near a sink. Do not leave it 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 capsules, or the capsules have passed their expiry date, return the unused medicine to your pharmacist.

Product description

What it looks like

OxyNorm capsules come in three strengths:

OxyNorm 5 mg - orange/beige capsules, printed ONR 5 mg.

OxyNorm 10 mg - white/beige capsules, printed ONR 10 mg.

OxyNorm 20 mg - pink/beige capsules, printed ONR 20 mg.

OxyNorm capsules come in blister packs containing 20 capsules.

Ingredients

OxyNorm capsules contain either 5 mg or 10 mg or 20 mg, of oxycodone hydrochloride, as the active ingredient.

The inactive ingredients in OxyNorm capsules are microcrystalline cellulose and magnesium stearate.

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

E172 (iron oxide), E132 (indigo carmine), E171 (titanium dioxide), sodium lauryl sulfate and gelatin.

The 5 mg OxyNorm capsules also contain E110 (sunset yellow FCF).

The capsules are printed in black ink which contains industrial methylated spirit, shellac, iron oxide black (E172), soya lecithin and butyl alcohol.

Identification

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

Blister pack

OxyNorm 5mg - AUST R 74145

OxyNorm 10mg - AUST R 74143

OxyNorm 20mg - AUST R 74141

Supplier

Mundipharma Pty Limited

ABN 87 081 322 509

Level 26, 6 O'Connell Street

Sydney, NSW, 2000

Date of preparation:

April 2006