

Mayne Pharma Oxycodone IR Tablets

oxycodone hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Mayne Pharma Oxycodone IR tablets. 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 oxycodone 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 Oxycodone is used for

Oxycodone belongs to a group of medicines called narcotic analgesics. Narcotic analgesics are used to relieve pain.

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.

Oxycodone can be addictive. If used for a long time Oxycodone may become habit forming causing mental and physical dependence. If abused it may become less able to reduce pain.

Oxycodone is available only with a doctor's prescription.

Before you take Oxycodone Tablets

When you must not take it

Do not take Oxycodone Tablets if you have an allergy to:

- any medicine containing oxycodone hydrochloride
- any of the ingredients listed at the end of this leaflet.
- any other similar medicines known as narcotic analgesics e.g. morphine, codeine, opium.

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

Do not take this medicine during pregnancy or during breastfeeding.

It may cause difficulty in breathing in an unborn or newborn child.

Women who are pregnant, planning to become pregnant or who are breastfeeding should discuss this with their doctor.

Do not give this medicine to children.

There is not enough information available to recommend the use of Oxycodone in children.

Do not take this medicine after the expiry date printed on the

pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

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 of the following medical conditions:

- muscle weakness
- underactive thyroid
- kidney disease
- liver disease
- low blood pressure
- if a male, prostate problems or difficulty passing urine
- bowel disorders

It may not be safe for you to take Oxycodone if you have these conditions. Your doctor will need to consider all these factors when advising you about taking Oxycodone.

If you have not told your doctor about any of the above, tell him/her before you start taking Oxycodone.

Taking other medicines

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

Some medicines and Oxycodone may interfere with each other.

These include:

- anaesthetics
- medicines used to thin the blood
- medicines used to treat epilepsy
- medicines used to help with sleeping
- blood pressure lowering medicines
- medicines used to treat mental health problems
- medicines used to treat anxiety or depression
- medicines used to treat 'flu' symptoms
- pain relievers
- medicines used to relieve stomach cramps or spasms
- (example) warfarin, a medicine used to prevent blood clots

These medicines and alcohol may be affected by Oxycodone or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Oxycodone.

How to take Oxycodone Tablets

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

The usual dose is ONE tablet every six hours.

Your doctor may prescribe a different dose for you. Be sure to follow your doctor's directions

about when and how to take Oxycodone.

How to take it

Swallow the tablet whole with a full glass of water.

When to take it

Oxycodone should be taken after meals or with milk.

How long to take it

The length of treatment will depend on your condition. Your doctor will advise you when to stop taking Oxycodone Tablets.

If you forget to take it

If it is less than 2-3 hours before your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

If you are not sure what to do, ask your doctor or pharmacist.

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

If you take 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 the nearest hospital, if you think that you or anyone else may have taken too much Oxycodone. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include feeling sleepy and/or difficulty in breathing which could lead to unconsciousness and loss of

muscle control. Your heart may stop and death may occur.

While you are using Oxycodone Tablets

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Oxycodone.

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.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not take Oxycodone to treat any other complaints 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 or lower the dosage without checking with your doctor.

If you have been taking this medicine for a long period of time and stop taking it suddenly, you may have unwanted side effects such as withdrawal symptoms. If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

Things to be careful of

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

This medicine may cause dizziness, light-headedness, tiredness, drowsiness in some people. It may affect alertness. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, 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.

Side effects

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

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

If you are over 65 years of age you may have an increased chance of getting side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- dizziness, light headedness, confusion
- drowsiness
- low blood pressure
- constipation
- vomiting
- nausea

The above list includes the more common side effects of your medicine.

Tell your doctor as soon as possible if you notice any of the following:

- difficulty passing urine
- decreased frequency of passing urine
- dry mouth
- sweating
- itchy rash
- muscle stiffness
- redness of the face
- loss of appetite
- faintness or feeling weak
- slow, abnormal or fast heart rate
- fall in blood pressure on standing
- decrease in body temperature
- restlessness
- severe headache due to increased pressure within the head
- changes of mood
- constriction of pupils.

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- unconsciousness
- inability to breathe properly
- severe dizziness, drowsiness or disorientation
- symptoms of allergy (e.g. itchy skin rash, skin blisters or discolouration of skin upon exposure to sunlight).

The above list includes serious side effects. You may need urgent medical attention or hospitalisation. These side effects are uncommon.

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.

High doses of Oxycodone can cause unconsciousness, heart failure, low blood pressure and an inability to breathe properly.

In long term use, physical dependence and tolerance may develop and the following withdrawal symptoms may be observed after Oxycodone is discontinued:

- body aches
- loose bowel motions or diarrhoea
- loss of appetite
- nervousness
- restlessness
- runny nose
- sneezing
- shivering
- stomach cramps
- nausea
- trouble with sleeping
- an increase in sweating and yawning
- weakness
- fast heart rate
- unexplained fever

These symptoms are mild if withdrawal from Oxycodone is gradual once it is no longer needed.

After using Oxycodone Tablets

Storage

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

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store Oxycodone 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.

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 what to do with any medicine that is left over.

Product description

What it looks like

White to off-white, round tablet.

One side is plain, the other side is scored and debossed "112".

The tablets come in packs of 10 and 20.

Ingredients

Mayne Pharma Oxycodone IR tablets contain 5 mg of oxycodone hydrochloride as the active ingredient.

- Lactose monohydrate
- microcrystalline cellulose
- maize starch
- Sodium starch glycollate type A
- Stearic acid
- Silicon dioxide

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

Manufacturer

Mayne Pharma Oxycodone IR tablets are distributed in Australia by:

Mayne Pharma International Pty
Ltd
1538 Main North Rd
Salisbury South, SA, 5106

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