

Oxyndone

oxycodone hydrochloride

Consumer Medicine Information

WARNING

Limitations of use

Oxyndone should only be used when your doctor decides that other treatment options are not able to effectively manage your pain or you cannot tolerate them.

Hazardous and harmful use

Oxyndone poses risks of abuse, misuse and addiction which can lead to overdose and death. Your doctor will monitor you regularly during treatment.

Life threatening respiratory depression

Oxyndone can cause life-threatening or fatal breathing problems (slow, shallow, unusual or no breathing), even when used as recommended. These problems can occur at any time during use, but the risk is higher when first starting Oxyndone and after a dose increase, if you are older or have an existing problem with your lungs. Your doctor will monitor you and change the dose as appropriate.

Use of other medicines while using Oxyndone

Using Oxyndone with other medicines that can make you feel drowsy such as sleeping tablets (e.g. benzodiazepines), other pain relievers, antihistamines, antidepressants, antipsychotics, gabapentinoids (e.g. gabapentin and pregabalin), cannabis and alcohol may result in severe drowsiness, decreased awareness, breathing problems, coma and death.

Your doctor will minimise the dose and duration of use; and monitor you for signs and symptoms of breathing difficulties and sedation. You must not drink alcohol while using Oxyndone.

What is in this leaflet

This leaflet answers some common questions about Oxyndone. 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 up 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 want to read it again later.

What Oxyndone is used for

This medicine is used for the short term management of severe pain.

This medicine belongs to a group of medicines called narcotic analgesics.

This medicine contains oxycodone hydrochloride as the active ingredient.

The active ingredient in this medicine works by binding to receptors called opioid receptors, which are in your central nervous system. This binding action changes your body's perception of pain throughout the central nervous system producing the pain relieving (analgesic) effect.

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

Your doctor may have prescribed it for another reason.

Oxyndone is only available with a doctor's prescription.

ADDICTION

You can become addicted to Oxyndone even if you take it exactly as prescribed. Oxyndone may become habit forming causing mental and physical dependence. If abused it may become less able to reduce pain.

DEPENDENCE

As with all other opioid containing products, your body may become used to you taking Oxyndone. Taking it may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop taking Oxyndone suddenly, so it is important to take it exactly as directed by your doctor.

TOLERANCE

Tolerance to Oxyndone may develop, which means that the effect of the medicine may

decrease. If this happens, more may be needed to maintain the same effect. Speak to your doctor if this occurs.

WITHDRAWAL

Continue taking your medicine for as long as your doctor tells you. If you stop taking this medicine suddenly, your pain may worsen and you may experience some or all of the following withdrawal symptoms:

- nervousness, restlessness, agitation, trouble sleeping or anxiety
- body aches, weakness or stomach cramps
- loss of appetite, nausea, vomiting or diarrhoea
- increased heart rate, breathing rate or pupil size
- watery eyes, runny nose, chills or yawning
- increased sweating

Oxyndone given to the mother during labour can cause breathing problems and signs of withdrawal in the newborn.

Before you take it

When you must not take it

Do not take Oxyndone if you have an allergy to:

- any medicine containing oxycodone hydrochloride
- any of the ingredients listed at the end of this leaflet
- any other narcotic analgesics such as morphine, codeine or 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 if you are pregnant.

It may affect your developing baby if you take it during pregnancy.

Do not breast-feed if you are taking this medicine.

The active ingredient in Oxyndone passes into breast milk and there is a possibility that your baby may be affected.

Do not give this medicine to children.

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

Do not use oxycodone if you currently have or have had any of the following:

- head injury
- brain tumour
- epilepsy or other convulsive disorders
- heart problems such as an irregular and/or rapid heartbeat
- chronic obstructive pulmonary disease, asthma or any other respiratory diseases
- severe headaches, or headaches due to due to raised pressure in the head.
- a history of alcohol or drug abuse
- a history of mental illness

Do not take this medicine if you are taking or have taken medicines for depression called Monoamine Oxidase Inhibitors (MAOs) within the last 14 days.

Do not take Oxyndone after the expiry date (EXP) printed on the packet or if the packaging is torn or shows signs of tampering.

It may not work as well if you take it after the expiry date. If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should be taking Oxyndone, consult 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 currently have or have had any of the following conditions:

- muscle weakness
- underactive thyroid
- kidney disease
- liver disease
- low blood pressure
- prostate problems or difficulty passing urine
- bowel disorders
- prescription or illicit drug addiction

If you have not told your doctor about any of the above, tell them before you start taking Oxyndone.

Taking other medicines

Tell your doctor about all the medicines you are taking, including any that you

may buy from pharmacies, health food shops or supermarkets.

Some medicines may interfere with oxycodone and these include:

- anaesthetics
- anticoagulants, 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 anxiety
- medicines used to treat depression
- medicines used to treat cold and flu symptoms
- other medicines used to relieve pain
- medicines, used to relieve nausea and vomiting
- atropine-like medicines, used to prevent travel sickness and for stomach cramps or spasms
- medicines used to treat chronic obstructive pulmonary disorder
- antipsychotic medicines, used to treat psychosis, schizophrenia or bipolar disorder
- antihistamine medicines, used to treat allergic skin conditions or hay fever
- any medicine containing naloxone and/or naltrexone, used to reverse the effects of narcotic analgesics

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

Your doctor or pharmacist has a more complete list of medicines to avoid while taking Oxycodone.

How to take Oxycodone

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 bottle, 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.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How to take it

Swallow Oxycodone with a full glass of water.

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.

If you have been using this medicine for a long period of time and it is no longer

needed to control pain DO NOT suddenly stop taking Oxycodone.

Your doctor may want you to gradually reduce the amount of Oxycodone you are taking before stopping completely in order to lessen the risk of withdrawal symptoms.

If you forget to take it

If it is less than 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.

This may increase the chance of you getting an unwanted side effect.

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

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

If you take too much (overdose)

If you or someone else receives too much (overdose), and experience one or more of the symptoms below, immediately call triple zero (000) for an ambulance. Keep the person awake by talking to them or gently shaking them every now and then. You should follow the above steps even if someone other than you have accidentally used Oxycodone that was prescribed for you. If someone takes an overdose, they may experience one or more of the following symptoms:

- Slow, unusual or difficult breathing
- Drowsiness, dizziness or unconsciousness
- Slow or weak heartbeat
- Nausea or vomiting
- Convulsions or fits
- Clumsiness or loss of coordination
- Difficulty walking
- Facial drooping
- Loss of vision
- Personality changes
- Trouble speaking
- Weak muscles

If you think you or someone else may have used too much Oxycodone, you should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

When seeking medical attention, take this leaflet and any remaining medicine with you to show the doctor. Also tell them about any other medicines or alcohol which may have been taken.

While you are taking it

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 all other doctors, dentists and pharmacists who are treating you that you are taking Oxycodone.

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 Oxycodone, tell your doctor immediately.

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

Things you must not do

Do not take any other medicines while you are taking oxycodone unless you have discussed this with your doctor.

This includes medicines you can buy without a prescription from a pharmacy, supermarket or health food shop.

Do not take Oxycodone to treat any complaint other than that directed by your doctor.

It may not be safe to take Oxycodone for another complaint.

Do not give Oxycodone to anyone else, even if their symptoms seem similar to yours.

It may not be safe for another person to take this medicine.

Do not stop taking it or lower or increase the dose without first checking with your doctor.

If you stop taking Oxycodone suddenly, your condition may worsen, you may have unwanted side effects, or you may experience withdrawal symptoms.

Your doctor will gradually reduce the amount you take each day before stopping this medicine completely.

Do not let yourself run out of medicine over the weekend or on holidays.

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

This medicine may impair the mental and physical ability needed to drive a car or operate heavy machinery. Oxycodone may cause drowsiness, sleepiness or dizziness in some people and affect alertness. Make sure you know how you react to it before you drive or operate machinery.

Things to be careful of

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 even if you do not think the problems are connected with the medication or they are not listed in this leaflet.

This medicine helps most people with their pain, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not.

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

All medicines can have side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and require medical attention.

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

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

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

- dizziness, light-headedness, and confusion
- drowsiness
- constipation
- vomiting
- nausea
- unusual tiredness or weakness

These are 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
- redness of the face
- loss of appetite
- faintness or feeling weak
- slow heart rate
- abnormal and fast heart rate
- irregular heart beat
- feeling light headed when standing up or when getting out of bed
- decrease in body temperature
- restlessness or nervousness
- changes of mood
- constriction of pupils
- hallucinations
- muscle rigidity
- severe headache due to increased pressure in the head.

These side effects are serious and may require medical attention.

Tell your doctor immediately, or go (or if you are a carer, take anyone else) to Accident and Emergency at your nearest hospital if you notice any of the following symptoms after taking Oxyndone:

- loss of consciousness
- difficulty or an 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).

These are uncommon but serious side effects. Urgent medical attention may be required to deal with these effects.

Other side effects not listed above may also occur in some people.

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

- nervousness, restlessness, agitation, trouble sleeping or anxiety
- body aches, weakness or stomach cramps
- loss of appetite, nausea, vomiting or diarrhoea

- increase heart rate, breathing rate or pupil size
- watery eyes, runny nose, chills or yawning
- increased sweating

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

Tell your doctor if you notice anything else that is making you feel unwell, even if you think the problems are not connected with this medicine and are not referred to in this leaflet.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After taking it

Storage

Keep Oxyndone tablets in their container until it is time to take them.

If you take them out of their container, they may not keep as well.

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

Do not store it or any other medication in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can ruin some medicines.

Keep it where young 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 Oxyndone or you find that they have passed their expiry date, ask your pharmacist what to do with any unused medicine.

Product description

What it looks like

Oxyndone 5 mg are dark blue, round, vaulted, biconvex film coated tablets. Available in PVC/PVDC/Al blister packs of 20 tablets.

Ingredients

Active ingredient:

Each Oxyndone tablet contains oxycodone hydrochloride 5 mg.

Inactive ingredients:

- lactose monohydrate
- microcrystalline cellulose
- magnesium stearate
- sodium starch glycollate type A
- colloidal anhydrous silica
- Opadry II complete film coating system 85G20477 blue (ARTG111601)

This medicine contains sugars (as lactose) and soy bean products.

Oxyndone tablets do not contain gluten, sucrose, tartrazine or any other azo dyes.

Supplier

Arrotex Pharmaceuticals Pty Ltd
15 – 17 Chapel Street,
Cremorne 3121 VIC Australia

Australian Registration number: 297760.

This leaflet was revised in December 2023.

Please check with your pharmacist that this is the latest version of the leaflet available.