

Consumer Medicine Information

# OXYCODONE CONTROLLED RELEASE TABLETS

Oxycodone hydrochloride

**Controlled release** tablets (Matrix Formulation)

5mg, 10 mg, 20 mg, 40 mg & 80 mg

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## What is in this leaflet

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Please read this leaflet carefully before you start taking Oxycodone Controlled Release Tablets.

This leaflet answers some common questions about Oxycodone Controlled Release Tablets. It does not contain all the available information. The most up-to-date Consumer Medicine Information can be downloaded from [www.medsafe.govt.nz](http://www.medsafe.govt.nz).

Reading this leaflet 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 Controlled Release Tablets against the benefits this medicine is expected to 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.

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## What Oxycodone Controlled Release Tablets are used for

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Oxycodone Controlled Release Tablets contain oxycodone hydrochloride. Oxycodone belongs to a group of medicines called opioid analgesics which are strong medicines used to treat or prevent pain.

Oxycodone Controlled Release Tablets are used to relieve moderate to severe persistent pain when other forms of treatment have not been effective.

Your doctor may have prescribed this medicine for another reason.

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

Oxycodone Controlled Release Tablets are only available with a doctor's prescription.

As with all strong painkillers, your body may become used to you taking Oxycodone Controlled Release Tablets. Taking it may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop taking oxycodone suddenly, so it is important to take it exactly as directed by your doctor.

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## Before you take Oxycodone Controlled Release Tablets

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Oxycodone Controlled Release Tablets are not suitable for everyone.

### ***When you must not take it***

#### **Do not take Oxycodone Controlled Release Tablets if you:**

- suffer from shallow breathing or have any breathing problems such as acute asthma, chronic bronchitis or impaired lung function
- are severely drowsy or have a reduced level of consciousness
- suffer from irregular or fast heartbeats or changes in the way the heart beats
- have heart problems or heart disease, including if this is due to long term lung disease
- have just drunk a large amount of alcohol, regularly drink large amounts of alcohol or have confusion and shaking due to stopping drinking alcohol
- suffer from convulsions, fits or seizures
- have a head injury, a brain tumour or have raised pressure within the head, brain or spinal cord
- have severe abdominal pain with bloating, cramps, vomiting or constipation
- have a condition where your stomach empties more slowly than it should, your small bowel does not work properly or you have just had an operation on your abdomen
- have severe liver or kidney disease
- are about to have an operation including surgery on your spine for pain relief in the next 24 hours or have had an operation within the last 24 hours
- are taking a medicine for depression called a monoamine oxidase inhibitor (MAOI) or have taken any in the last two weeks
- have been given the 80 mg strength and you have not used any opioid medicine before.

**Do not take Oxycodone Controlled Release Tablets if you are allergic to any medicine containing oxycodone, opioid painkillers, or any of the ingredients listed at the end of this leaflet.**

#### **Do not take it if you are pregnant or intend to become pregnant.**

Like most medicines of this kind, Oxycodone Controlled Release Tablets are not recommended to be taken during pregnancy. Extended use of oxycodone during pregnancy can cause withdrawal symptoms in newborns. Your doctor will discuss the risks and benefits of taking it if you are pregnant.

**Do not take it after the expiry date (EXP) printed on the pack.**

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

**Do not take it if the packaging is torn or shows signs of tampering.**

**If you are not sure whether you should start taking Oxycodone Controlled Release Tablets, talk to your doctor or pharmacist.**

### ***Before you start to take it***

**Tell your doctor or pharmacist if you have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if you have or have had any medical conditions, especially the following:**

- low blood pressure including from having low blood volume
- increased prostate size or difficulty passing urine
- chronic lung, liver or kidney disease
- problems with or recent surgery on your gall bladder or bile duct
- inflammation of the pancreas
- adrenal glands not working properly
- underactive thyroid gland
- inflammatory bowel disease or recent abdominal surgery
- severe mental condition involving losing contact with reality, hearing voices or an inability to think clearly
- an addiction or history of abuse of alcohol, opioids or other drugs.

**This medicine is not recommended to be taken during labour.**

Oxycodone given to the mother during labour can cause breathing problems in the newborn.

**Tell your doctor if you are breast-feeding or planning to breast-feed.**

The active ingredient in Oxycodone Controlled Release Tablets passes into breast milk and there is a possibility that your baby may be affected. Your doctor can discuss with you the risks and benefits involved.

**Tell your doctor if you intend to become pregnant.**

Extended use of oxycodone can cause problems conceiving, irregular periods and sexual problems.

**Do not give Oxycodone Controlled Release Tablets to a child aged 12 years and under.**

There is not enough information to recommend the use of this medicine for children under 12 years old.

**If you have not told your doctor or pharmacist about any of the above, tell them before you start taking Oxycodone Controlled Release Tablets.**

### ***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.**

**Tell any health professional who is prescribing a new medicine for you that you are taking Oxycodone Controlled Release Tablets.**

Some medicines and Oxycodone Controlled Release Tablets may interfere with each other. These include:

- medicines to treat depression, psychiatric or mental disorders. Medicines to treat depression belonging to a group called monoamine oxidase inhibitors (MAOIs) must be stopped 14 days before Oxycodone Controlled Release Tablets are taken.
- medicines to relieve allergy symptoms
- medicines to help you sleep
- medicines to put you to sleep during an operation or procedure
- medicines to relax your muscles
- medicines to lower blood pressure
- quinidine and other medicines to treat the heart
- medicines to thin the blood, e.g. coumarin derivatives such as warfarin
- cimetidine, a medicine used to treat ulcers
- medicines to relieve stomach cramps or spasms, to prevent travel sickness or to treat Parkinson's disease
- medicines to stop nausea or vomiting e.g. metoclopramide
- other pain relievers including other opioids
- ketoconazole, a medicine to treat fungal infections
- alcohol.

The above medicines may be affected by Oxycodone Controlled Release Tablets, or may affect how well they work. You may need different amounts of Oxycodone Controlled Release Tablets, or take them at different times, 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 Controlled Release Tablets.

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## **How to take Oxycodone Controlled Release Tablets**

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**Read the label carefully and follow all directions given to you by your doctor and pharmacist.**

They may differ from the information contained in this leaflet.

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

### ***How much to take***

**Your doctor will tell you exactly how much Oxycodone Controlled Release Tablets you should take.**

If you take the wrong dose, Oxycodone Controlled Release Tablets may not work as well and your problem may not improve.

**Ask your doctor or pharmacist if you are unsure of the correct dose for you.**

This depends on your condition and whether or not you are taking any other medicines.

Follow the instructions given to you by your doctor and pharmacist exactly.

### ***How to take it***

**Swallow the tablet(s) with a full glass of water or other fluid. Take them with or without food.**

**Do not break, crush, chew or dissolve the tablets.**

The tablets may release all their contents at once if broken, chewed, crushed or dissolved, which can be dangerous and cause serious problems, such as an overdose or even death.

**If you have trouble swallowing your tablets, talk to your doctor.**

**You must only take Oxycodone Controlled Release Tablets by mouth.**

Taking this medicine in a manner other than that prescribed by your doctor can be harmful to your health.

### ***When to take it***

**Take Oxycodone Controlled Release Tablets every 12 hours.**

**Take Oxycodone Controlled Release Tablets regularly to control the pain.**

Taking them at the same time each day will have the best effect and will mean that the onset of pain is prevented. If, however, you begin to experience pain ('breakthrough pain') and you are taking your Oxycodone Controlled Release Tablets as prescribed, contact your doctor as your dosage may have to be reviewed.

### ***How long to take it***

**Continue taking the medicine for as long as your doctor tells you.**

If you stop taking this medicine suddenly, your pain may worsen and you may experience withdrawal symptoms such as:

- body aches
- loss of appetite, nausea, stomach cramps or diarrhoea
- fast heart rate
- sneezing or runny nose
- chills, tremors, shivering or fever
- trouble sleeping
- increased sweating and yawning
- weakness
- nervousness or restlessness.

**If you are unsure whether you should stop taking Oxycodone Controlled Release Tablets, talk to your doctor or pharmacist.**

### ***If you forget to take it***

**If it is almost time for your next dose, skip the dose you missed and take the next dose when you are meant to.**

**Do not try to make up for missed doses by taking more than one dose at a time.**

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

**If there is still a long time to go before your next dose, take it as soon as you remember, and then go back to taking it as you would normally.**

**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 hints.**

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## **While you are taking Oxycodone Controlled Release Tablets**

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### ***Things you must do***

**Take Oxycodone Controlled Release Tablets exactly as your doctor has prescribed.**

**If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Oxycodone Controlled Release Tablets. Likewise, tell any other doctors, dentists and pharmacists who are treating you that you are taking this medicine.**

**If you are going to have surgery, tell the surgeon and 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.**

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

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

Tolerance to oxycodone may develop, which means that the effect of the medicine may decrease. If this happens, your doctor may increase the dose so that you get adequate pain relief.

**See your doctor if you feel that your condition is not improving or is getting worse.**

**Keep enough Oxycodone Controlled Release Tablets with you to last over weekends and holidays.**

### ***Things you must not do***

**Do not give your medicine to anyone else, even if they have the same condition as you.**

This medicine is only intended for the person it has been prescribed for.

**Do not take Oxycodone Controlled Release Tablets to treat any other complaints unless your doctor tells you to.**

**Do not stop taking Oxycodone Controlled Release Tablets or change the dosage without checking with your doctor.**

Over time your body may become used to you taking oxycodone so if you stop taking it suddenly, your pain may worsen and you may have unwanted side effects such as withdrawal symptoms. This is called physical dependence. If you need to stop taking this medicine, your doctor will gradually reduce the amount you take each day, if possible, before stopping the medicine completely.

**Do not drink alcohol while you are taking Oxycodone Controlled Release Tablets.**

Alcohol use could increase serious side effects of oxycodone, such as sleepiness, drowsiness and slow or shallow breathing.

### ***Things to be careful of***

**Do not drive or operate machinery until you know how Oxycodone Controlled Release Tablets affect you.**

It may cause drowsiness, dizziness, hallucinations, disorientation, blurred vision or other vision problems or may affect alertness.

**Discuss these aspects and any impact on your driving or operating machinery with your doctor.**

**If you feel light-headed, dizzy or faint, get up slowly when getting out of bed or standing up. You may feel light-headed when you begin to take these tablets.**

This is because your blood pressure is falling suddenly. 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.**

**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.

**Tell your doctor if you suffer from nausea or vomiting when taking Oxycodone Controlled Release Tablets.**

If you vomit after your dose, your pain may come back, as you may not have absorbed your medicine. If this happens, speak to your doctor. Your doctor may prescribe some medicine to help you stop vomiting.

**Tell your doctor if taking Oxycodone Controlled Release Tablets causes constipation.**

Your doctor can advise you about your diet, the proper use of laxatives and suitable exercise you can do to help you manage this.

There is potential for abuse of oxycodone and the development of addiction to oxycodone. It is important that you discuss this issue with your doctor.

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## In case of overdose

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### *If you take too much*

Immediately telephone your doctor, or the Poisons Information Centre (telephone 0800 POISON or 0800 764 766), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Oxycodone Controlled Release Tablets.

**Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

Symptoms of an overdose may include difficulties in breathing, becoming drowsy and tired, lack of muscle tone, having cold or clammy skin, constricted pupils, very low blood pressure or slow heart rate, becoming unconscious or death.

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

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## Side effects

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

Like all medicines, Oxycodone Controlled Release Tablets may occasionally cause side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

**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:**

- mild abdominal problems such as diarrhoea, feeling sick, loss of appetite or constipation
- dry mouth, hiccups, sore throat, trouble swallowing or changes in voice
- sweating and flushing
- feeling anxious or nervous, trouble sleeping or abnormal dreams
- trouble with your balance
- new problems with your eyesight
- skin rash, itching, chills or fever
- fatigue
- muscle problems such as spasms or twitching
- impotence
- decreased sexual drive
- changes in menstrual bleeding
- swelling of legs or ankles.



**Tell your doctor as soon as possible if you notice any of the following and they worry you:**

- stomach discomfort, vomiting, indigestion or abdominal pain
- abnormal thinking, changes in mood or feeling deep sadness
- drowsiness, fainting or dizziness especially when standing up
- slow or noticeable heartbeats
- headache or confusion
- unusual weakness, loss of strength or trouble walking
- changes in passing urine such as the volume passed, pain or feeling the need to urinate urgently.

These may be serious side effects. You may need urgent medical attention.

**Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following:**

- serious allergic reaction (shortness of breath, wheezing, shallow or difficult breathing, swelling of the face, lips, tongue, throat or other parts of the body, rash, itching or hives on the skin)
- seizures, fits or convulsions
- fast or irregular heartbeats
- chest pain or chest tightness.

These are very serious side effects; you may need urgent medical attention or hospitalisation.

**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.

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

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## **After taking Oxycodone Controlled Release Tablets**

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### **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 Oxycodone Controlled Release Tablets in a cool dry place where the temperature stays below 25°C.**

**Do not store it or any other medicine in the bathroom, near a sink, or on a window sill.**

**Do not leave it in the car.**

Heat and damp can destroy some medicines.

**Keep it and any other medicine 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.

**Do not keep Oxycodone Controlled Release Tablets past their expiry date.**

### ***Disposal***

**Return any unused medicine, and any medicine past its expiry date (as shown on the labelling) to your pharmacy.**

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## **Product description**

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### ***What it looks like***

Oxycodone Controlled Release Tablets are available in blister packs of 20 tablets. There are 5 different strengths:

The **5 mg** tablets are **light blue**, round, biconvex controlled release tablets with black imprint '5' on one side and a diameter of approximately 7.1 mm.

The **10 mg** tablets are **white**, round, biconvex controlled release tablets with black imprint '10' on one side and a diameter of approximately 7.1 mm.

The **20 mg** tablets are **light pink**, round, biconvex controlled release tablets with black imprint '20' on one side and a diameter of approximately 7.1 mm.

The **40 mg** tablets are **light orange to ochre**, round, biconvex controlled release tablets with black imprint '40' on one side and a diameter of approximately 7.1 mm.

The **80 mg** tablets are **green**, round, biconvex controlled release tablets with white imprint '80' on one side and a diameter of approximately 8.8 mm.

### ***Ingredients***

#### Active ingredient:

- oxycodone hydrochloride

#### Inactive ingredients:

- lactose monohydrate
- ammonio methacrylate copolymer Type B
- povidone
- talc
- triacetin
- stearyl alcohol

- magnesium stearate
- hypromellose
- macrogol 400
- titanium dioxide
- brilliant blue FCF (5 mg tablets only)
- iron oxide red (20 mg and 40 mg tablets only)
- iron oxide yellow (40 mg and 80 mg tablets only)
- indigo carmine aluminium lake (80 mg tablets only)
- printing ink

Oxycodone Controlled Release Tablets contain lactose. They do not contain tartrazine or any other azo dyes.

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## **Sponsor details**

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***Distributed in New Zealand by:***

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## **Date of preparation**

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