

OxyContin(R) tablets

Oxycodone hydrochloride

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start taking OxyContin tablets.

This leaflet answers some of the common questions about OxyContin 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 OxyContin against the benefits they expect it will have for you.

Use OxyContin 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 OxyContin(R) tablets are used for

OxyContin tablets are used to relieve moderate to severe persistent pain when other forms of treatment have not been effective.

OxyContin belongs to a class of drugs known as opioid analgesics.

Opioid analgesics such as OxyContin 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

OxyContin, so if you suddenly stop taking OxyContin, 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 OxyContin affects you.

Before you take OxyContin(R) tablets

When you must not take it

1. You have allergies to:

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

2. 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.

- 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 OxyContin 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 OXYCONTIN TABLETS IF THE PACKAGING IS TORN OR SHOWS ANY SIGNS OF TAMPERING, OR IF THE TABLETS 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
- * severe mental condition involving losing contact with reality, inability to think clearly

2. You are pregnant or plan to become pregnant.

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

3. You are breastfeeding or plan to breastfeed.

Your doctor will discuss the risks and benefits of taking OxyContin when breastfeeding.

If you have not told your doctor about any of the above, tell them before you take any OxyContin tablets.

OXYCONTIN IS NOT RECOMMENDED FOR CHILDREN UNDER 12 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 OxyContin. 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 OxyContin. 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 OxyContin.

How to take OxyContin(R) tablets

How much to take

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

The amount of OxyContin 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 OxyContin tablets whole with a full glass of water or other fluid.

Do not chew, crush or dissolve tablets.

OxyContin tablets were designed to work properly only if swallowed whole. They may release all their contents at once if broken, chewed or crushed, resulting in a risk of overdose.

When to take it

Take this medicine as directed by your doctor.

OxyContin tablets should be taken every twelve hours.

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

OxyContin must be taken regularly to control the pain. Taking OxyContin at regular time intervals means that the onset of pain is prevented. OxyContin should not be taken when you feel you need it, as this will cause some pain to be experienced.

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

How long to take it

Continue taking OxyContin 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 8am and 8pm.

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 131 126), or go to casualty at your nearest hospital, if you think you or anyone else may have taken too much OxyContin. Do this even if there are no signs of discomfort or poisoning. Also report any other medicines or alcohol which has been taken. You may need urgent medical attention. Keep telephone numbers for these places handy.

If someone takes too many tablets, they will probably become drowsy, tired, confused, have a very low blood pressure, experience difficulties in breathing and possibly become unconscious.

While you are taking OxyContin(R) tablets

Things you must do

Take OxyContin 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 OxyContin tablets.

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

Keep enough OxyContin tablets with you to last over weekends and holidays.

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

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

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

Things you must not do

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

OxyContin 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 OxyContin or anything else that maybe dangerous if you are drowsy.

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

Do not take alcohol while being treated with OxyContin.

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

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

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

Do not stop taking OxyContin or lower dosage, without checking with your doctor.

OxyContin 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 OxyContin affects you.

You may feel drowsy when you begin to take OxyContin tablets. 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 OxyContin tablets. 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.

OxyContin 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 OxyContin.

OxyContin helps most people with moderate to severe pain, but they 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, coughing increased, 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, unconscious, 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.

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 OxyContin.

Ask your doctor if you don't 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 OxyContin 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 OxyContin, so if you suddenly stop taking OxyContin, you may experience some symptoms of withdrawal. It is important to discuss this issue with your doctor.

After using OxyContin(R) tablets

Storage

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

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

OxyContin tablets should be kept in a cool, dry place, where the temperature stays below 25 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 OxyContin, or the tablets have passed their expiry date, return the unused medicine to your pharmacist.

Product description

What it looks like

OxyContin tablets come in seven strengths:

OxyContin 5 mg - round, pale blue, with OC on one side and 5 on the other

OxyContin 10 mg - round, white, with OC on one side and 10 on the other

OxyContin 15 mg - round, grey, with OC on one side and 15 on the other

OxyContin 20 mg - round, pink, with OC on one side and 20 on the other

OxyContin 30 mg - round, brown, with OC on one side and 30 on the other

OxyContin 40 mg - round, yellow, with OC on one side and 40 on the other

OxyContin 80 mg - round, green, with OC on one side and 80 on the other

OxyContin tablets come in boxes containing 20 tablets.

Ingredients

OxyContin tablets contain either 5 mg, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg or 80 mg, of oxycodone hydrochloride, as the active ingredient.

The tablets also contain lactose, povidone, Eudragit RS 30D (solids), glycerol triacetate, stearyl alcohol, talc and magnesium stearate. All tablets are coated with hypromellose, titanium dioxide (E171) and macrogol 400.

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

OxyContin 5 mg - CI42090 (brilliant blue)

OxyContin 10 mg - hydroxypropylcellulose

OxyContin 15 mg - E172 (iron oxide)

OxyContin 20 mg - polysorbate 80, E172 (iron oxide)

OxyContin 30 mg - E172 (iron oxide)

OxyContin 40 mg - polysorbate 80, E172 (iron oxide)

OxyContin 80 mg - hydroxypropylcellulose, E172 (iron oxide) and E132 (indigo carmine)

Identification

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

OxyContin 5 mg - AUST R 93732

OxyContin 10 mg - AUST R 68187

OxyContin 15 mg - AUST R 143102

OxyContin 20 mg - AUST R 68190

OxyContin 30 mg - AUST R 143173

OxyContin 40 mg - AUST R 68191

OxyContin 80 mg - AUST R 68193

Supplier

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