

Oxycodone Sandoz®

Oxycodone hydrochloride modified release tablet

Consumer Medicine Information

WARNING:

Limitations of use

Oxycodone Sandoz 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

Oxycodone Sandoz 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

Oxycodone Sandoz 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 Oxycodone Sandoz 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 Oxycodone Sandoz

Using Oxycodone Sandoz 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; monitor you for signs and symptoms of breathing difficulties and sedation. You must not drink alcohol while using Oxycodone Sandoz.

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Oxycodone Sandoz.

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 this medicine 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 SANDOZ IS USED FOR

This medicine is used to relieve severe pain when other forms of treatment have failed or are otherwise inappropriate to provide sufficient management of pain.

It contains the active ingredient oxycodone hydrochloride.

Oxycodone hydrochloride belongs to a class of drugs known as opioid analgesics.

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

There is not enough information to recommend the use of this medicine

for children under the age of 12 years.

This medicine is available only with a doctor's prescription.

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.

BEFORE YOU TAKE OXYCODONE SANDOZ

Long-term use of oxycodone tablets may result in a decrease in sex hormone levels which may affect sperm production in men and the menstrual cycles in females. Talk to your doctor if you have concerns.

When you must not take it

Do not take this medicine if you have an allergy to:

- oxycodone hydrochloride, or to any of the other ingredients listed at the end of this leaflet under Product Description
- any other similar medicines known as opioid analgesics, e.g. morphine or codeine.

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 have or have had any of the following medical conditions:

- suffer from shallow breathing or have any breathing problems such as acute asthma, respiratory depression (breathing slows or weakens) or other obstructive airways disease
- severe drowsiness or have a reduced level of consciousness
- irregular or rapid heartbeats or changes in the way the heart beats
- heart problems or heart disease including if due to long term lung disease
- fits, convulsions or seizures
- head injury, brain tumour, severe headaches or have raised pressure within the head, brain or spinal cord
- severe abdominal pain with bloating, cramps, vomiting or constipation
- a condition where your stomach empties more slowly than it should or any condition that obstructs the stomach/bowel or affects bowel transit (movement of food or ingested material along the bowel)
- have swallowing difficulties of narrowing of the oesophagus
- severe liver or kidney disease
- severe depression

- a condition where you have high levels of carbon dioxide in your blood.

Do not take this medicine if:

- you are taking a medicine for depression called monoamine oxidase inhibitor, or you have taken any in the last two weeks
- you have just drunk a large amount of alcohol, regularly drink large amounts of alcohol or have confusion and shaking due to stopping drinking alcohol
- you 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
- you have been given the 80mg strength and have not used any opioid medicine before.

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:

- have sleep apnoea (temporarily stopping breathing while you sleep)
- low blood pressure including from having low blood volume
- chronic lung, liver or kidney disease
- stomach pains or constipation or inflammatory bowel disease or recent abdominal surgery
- diverticulitis (inflammation of bowel wall)
- increased prostate size or difficulty passing urine

- narrowing of the urinary tract
- problems or recent surgery of your gall bladder or bile duct
- inflammation of the pancreas
- disorientation, hallucination, dizziness standing up or severe headaches
- adrenal glands not working properly
- under-active thyroid gland
- oesophageal, stomach or intestinal disorders (including cancer in these areas) resulting in narrowing of the oesophagus, stomach or intestines
- 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.

Pregnancy and breastfeeding

Do not take this medicine if you are pregnant or intend to become pregnant whilst taking this medicine.

It may affect your developing baby if you take it during pregnancy. Like most medicines of this kind, Oxycodone Sandoz tablets are not recommended to be taken during pregnancy. Your doctor will discuss the risks of taking it if you are pregnant.

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 breastfeeding or plan to breastfeed.

Oxycodone can pass into the breastmilk and can affect the baby. Your doctor can discuss with you the risks and benefits involved.

Addiction

You can be addicted to Oxycodone Sandoz even if you take it exactly as prescribed. Oxycodone Sandoz 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 Oxycodone Sandoz. Taking it may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop taking Oxycodone Sandoz suddenly, so it is important to take it exactly as directed by your doctor.

Tolerance

Tolerance to Oxycodone Sandoz may develop, which means that the effect of the medicine may decrease. If this happens, more may be needed to maintain the same effect.

Withdrawal

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

Oxycodone Sandoz contains lactose. If you have been told by your doctor that you have intolerance to some sugars, tell your doctor before taking it.

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

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 Sandoz may interfere with each other. These include:

- medication for depression, psychiatric or mental disorders.
- medicines to treat depression belonging to a group called monoamine oxidase inhibitors must be stopped 14 days before Oxycodone Sandoz tablets are taken.
- antidepressants e.g. fluoxetine, paroxetine
- medication 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
- cimetidine, a medicine to treat stomach ulcers or heartburn
- medicines to relieve stomach cramps or spasms, to prevent travel sickness
- medicines to treat Parkinson's disease
- medicines to treat urinary incontinence
- medicines to stop nausea or vomiting e.g. metoclopramide
- other pain relievers including other opioids
- ketoconazole, a medicine to treat fungal infections
- ritonavir, an antiviral medication
- macrolide antibiotics, e.g. clarithromycin, rifampin
- medicines used to treat convulsions e.g. carbamazepine, phenytoin
- medicine to treat HIV infection and AIDs e.g. ritonavir
- St. John's wort (a herbal preparation)
- alcohol
- grapefruit and grapefruit juice

- medicines to thin the blood e.g. coumarin derivatives such as warfarin
- medicines to treat epilepsy, pain and anxiety e.g. gabapentin and pregabalin.

These medicines or alcohol may be affected by Oxycodone Sandoz or may affect how well it works. They may increase the side effects of Oxycodone Sandoz. 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 this medicine.

HOW TO TAKE OXYCODONE SANDOZ

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, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you exactly how much to take.

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

How to take it

Swallow Oxycodone Sandoz tablets whole with a full glass of water or other fluid.

Oxycodone Sandoz tablets should be taken one tablet at a time with enough water to ensure complete swallowing immediately after placing it in the mouth.

Do not pre-soak, lick or wet the tablet before placing in your mouth.

Do not break, chew, crush or dissolve the tablets. This medicine

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

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

You must only take Oxycodone Sandoz tablets by the mouth.

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

There are no data on rectal administration of Oxycodone Sandoz tablets, therefore rectal administration of Oxycodone Sandoz is not recommended.

When to take Oxycodone Sandoz

Take this medicine as directed by your doctor.

This medicine should be taken every twelve hours.

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

This medicine must be taken regularly to control the pain. Taking this medicine at regular time intervals means that the onset of pain is prevented. This medicine 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 Oxycodone Sandoz.

How long to take Oxycodone Sandoz

Continue taking your medicine for as long as your doctor recommends.

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 forget to take it

If you forget to take a dose, contact your doctor or pharmacist for advice.

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 to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

If you or someone else receive too much (overdose), and experience one or more symptoms below, 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 steps even if someone other than you have accidentally used Oxycodone Sandoz 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 of fits**

If you or someone else may have taken too much Oxycodone

Sandoz, you should immediately telephone your doctor or the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764766) 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 Sandoz. Do this even if there are no signs of discomfort or poisoning.

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 which have been taken.

WHILE YOU ARE TAKING OXYCODONE SANDOZ

Things you must do

Take this medicine exactly as your doctor has prescribed.

Before you start on a new medicine, remind your doctor and pharmacist that you are taking Oxycodone Sandoz.

Visit your doctor regularly for a check-up, and always discuss any problems or difficulties during or after taking this medicine.

Tell your doctor if your pain is getting worse, or if 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 review your dose so that you get adequate pain relief.

Keep enough of this medicine with you to last over weekends and holidays.

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.

Things you must not do

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

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

Do not take this medicine for a longer time than your doctor has prescribed.

Do not take alcohol while being treated with this medicine.

Drinking alcohol whilst taking Oxycodone Sandoz tablets may make you feel more sleepy and increase the risk of serious side effects, such as shallow breathing with the risk of stopping breathing and loss of consciousness.

Do not stop taking this medicine, exceed the dose recommended or change 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.

This medicine should be taken strictly according to your doctor's instructions.

Things to be careful of

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

Oxycodone 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.

Make sure you know how you react to this medicine before you drive a car, operate machinery, or do anything else that could be dangerous if you are drowsy, dizzy or not alert.

You may feel drowsy when you begin to take Oxycodone Sandoz 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.

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

Standing up slowly 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.

Tell your doctor if you suffer from nausea or vomiting when taking Oxycodone Sandoz.

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.

Tell your doctor if taking this medicine causes constipation.

Your doctor can advise you about your diet, the proper use of laxatives and 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.

SIDE EFFECTS

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

This medicine helps most people with 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. As for other medicines of this type, that is opioid analgesics, many side effects tend to reduce over time, with the exception of constipation. This means that the longer you take this medicine, the less it may cause problems for you. Your doctor has weighed the risks of this medicine against the benefits they expect it will have for you.

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:

- mild abdominal problems, such as diarrhoea, feeling sick (nausea), loss of appetite or constipation
- muscle problems such as spasms or twitching or tremors
- sore throat, dry mouth, hiccups, trouble swallowing or changes in voice
- excessive sweating
- skin rash, itching, fever, chills or sweating
- feeling anxious or nervous, trouble sleeping or abnormal dreams
- trouble with your balance
- new problems with your eyesight
- swelling of legs or ankles
- absence of menstrual periods
- impotence

- decreased sexual drive

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
- choking, gagging, regurgitation, tablets stuck in throat or trouble swallowing the tablets
- 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
- fatigue, feeling of tiredness drowsiness or lack of energy
- changes in passing urine such as the volume passed, pain or feeling the need to urinate urgently.

The above list includes serious side effects that may require medical treatment.

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

- your breathing slows or weakens
- you have an 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.

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

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

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

Ask your doctor if you don't understand anything in this list.

AFTER TAKING OXYCODONE SANDOZ

Storage

Keep your medicine in the original container.

If you take it out of its original container it may not keep well.

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

Do not store Oxycodone Sandoz 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

Oxycodone Sandoz comes in five strengths:

Oxycodone Sandoz 5 mg - blue, round, biconvex modified release tablets.

Oxycodone Sandoz 10 mg - white, round, biconvex modified release tablets.

Oxycodone Sandoz 20 mg - pink, round, biconvex modified release tablets.

Oxycodone Sandoz 40 mg - yellow, round, biconvex modified release tablets.

Oxycodone Sandoz 80 mg - green, round, biconvex modified release tablets.

Available in blister packs of 28 tablets.

Ingredients

Active ingredients:

- Oxycodone Sandoz 5 mg - 5 mg oxycodone hydrochloride
- Oxycodone Sandoz 10 mg - 10 mg oxycodone hydrochloride
- Oxycodone Sandoz 20 mg - 20 mg oxycodone hydrochloride
- Oxycodone Sandoz 40 mg - 40 mg oxycodone hydrochloride
- Oxycodone Sandoz 80 mg - 80 mg oxycodone hydrochloride

Inactive ingredients:

Excipients core:

- maize starch
- behenoyl polyoxyglycerides
- lactose monohydrate
- medium chain triglycerides
- copovidone
- castor oil - hydrogenated
- colloidal anhydrous silica
- magnesium stearate

Excipients coating:

- hypromellose
- microcrystalline cellulose
- stearic acid
- titanium dioxide
- indigo carmine aluminium lake (5mg tablets only)
- 815063 Spectracol Green Lake (80mg tablets only)
- iron oxide red (20 mg tablets only)
- iron oxide yellow (40 mg tablets only)
- iron oxide black (80 mg tablets only)

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

Supplier

Sandoz Pty Ltd
ABN 60 075 449 553

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5 mg tablets: AUST R 153605
(blister packs)

10 mg tablets: AUST R 153597
(blister packs)

20 mg tablets: AUST R 153615
(blister packs)

40 mg tablets: AUST R 153611
(blister packs)

80 mg tablets: AUST R 153591
(blister packs)