

Oxycodone Sandoz®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

1. Why am I using Oxycodone Sandoz?

Oxycodone Sandoz contains the active ingredient oxycodone hydrochloride. Oxycodone Sandoz is used to relieve severe pain when other forms of treatment have failed or are otherwise inappropriate to provide sufficient management of pain.

For more information, see Section [1. Why am I using Oxycodone Sandoz?](#) in the full CMI.

2. What should I know before I use Oxycodone Sandoz?

Do not use if you have ever had an allergic reaction to oxycodone hydrochloride or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Oxycodone Sandoz?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Oxycodone Sandoz and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Oxycodone Sandoz?

- Your doctor will tell you exactly how much to take.
- Follow the instructions given to you by your doctor or your pharmacist.
- You must only take Oxycodone Sandoz by mouth.

More instructions can be found in Section [4. How do I use Oxycodone Sandoz?](#) in the full CMI.

5. What should I know while using Oxycodone Sandoz?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Oxycodone Sandoz.• If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.• 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.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly.• 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.
Driving or using machines	<ul style="list-style-type: none">• Oxycodone Sandoz may cause dizziness, light-headedness, tiredness, drowsiness in some people. It may affect alertness.
Drinking alcohol	<ul style="list-style-type: none">• Do not drink alcohol while you are taking this medicine.
Looking after your medicine	<ul style="list-style-type: none">• Store below 25°C.• Keep your tablets in the pack until it is time to take them.

For more information, see Section [5. What should I know while using Oxycodone Sandoz?](#) in the full CMI.

6. Are there any side effects?

Oxycodone Sandoz may cause constipation, nausea, vomiting, dizziness, drowsiness and be habit forming if taken frequently or over long periods.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

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.

Oxycodone Sandoz®

Active ingredient(s): *oxycodone hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Oxycodone Sandoz. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Oxycodone Sandoz.**

Where to find information in this leaflet:

- [1. Why am I using Oxycodone Sandoz?](#)
- [2. What should I know before I use Oxycodone Sandoz?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Oxycodone Sandoz?](#)
- [5. What should I know while using Oxycodone Sandoz?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Oxycodone Sandoz?

Oxycodone Sandoz contains the active ingredient oxycodone hydrochloride. Oxycodone hydrochloride belongs to a group of medicines called opioid analgesics.

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

Your doctor, however, may prescribe it for another purpose.

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

As with all strong painkillers, 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.

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

2. What should I know before I use Oxycodone Sandoz?

Warnings

Do not use Oxycodone Sandoz if:

- you are allergic to oxycodone hydrochloride, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you have any breathing problems such as acute asthma, respiratory depression (breathing slows or weakens) or other obstructive airways disease
- you are severely drowsy or have a reduced level of consciousness
- you suffer from irregular heartbeats or changes in the way the heart beats
- you have heart disease due to long term lung disease
- you have just consumed a large amount of alcohol, regularly consume large amounts of alcohol or have confusion and shaking due to alcohol withdrawal
- you suffer from convulsions, fits or seizures
- you have a head injury, a brain tumour or have raised pressure within the head, brain or spinal cord
- you have sudden, severe abdominal pain

- you have 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)
- you have swallowing difficulties or narrowing of the oesophagus
- you have severe liver or kidney disease
- 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 take a medicine for depression called a 'monoamine oxidase inhibitor' or have taken any in the last two weeks.

Do not give this medicine to a child younger than 12 years of age.

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes
- have had any medical conditions, especially the following:
 - sleep apnoea (temporarily stopping breathing while you sleep)
 - low blood pressure
 - increased prostate size or difficulty passing urine
 - chronic lung, liver or kidney disease
 - disease of your gall bladder or bile duct
 - inflammation of the pancreas
 - underactive adrenal glands
 - underactive thyroid gland
 - inflammatory bowel disease or recent abdominal surgery
 - diverticulitis (inflammation of bowel wall)
 - 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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. This medicine is not recommended to be taken during labour.

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

Talk to your doctor if you are breastfeeding or intend to breastfeed. Oxycodone can pass into the breastmilk and can affect the baby. Your doctor can discuss with you the risks involved.

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

Like most medicines of this kind, Oxycodone Sandoz is not recommended to be taken during pregnancy. Your doctor will discuss the risks of taking it if you are pregnant.

Addiction

You can become 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 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.

3. What if I am taking other medicines?

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

Some medicines may interfere with Oxycodone Sandoz and affect how it works.

These medicines include:

- medicines to treat 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 is taken
- antidepressants e.g. fluoxetine, paroxetine
- 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 treat convulsions e.g. phenytoin, carbamazepine
- medicines to thin the blood e.g. coumarin derivatives such as warfarin
- cimetidine, a medicine to treat stomach ulcers or heartburn
- medicines to relieve stomach cramps or spasms, to prevent travel sickness or symptoms of allergies
- 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
- antifungals e.g. ketoconazole
- antibiotics e.g. clarithromycin, rifampin
- medicine to treat HIV infection and AIDS e.g. ritonavir
- alcohol
- St John's wort (a herbal preparation)
- grapefruit and grapefruit juice.
- medicines to treat epilepsy, pain, and anxiety e.g. gabapentin and pregabalin.

These medicines, dietary supplements or alcohol may be affected by Oxycodone Sandoz, may affect how well Oxycodone Sandoz works or may increase side effects. You may need to use different amounts of your medicines, or take different medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Oxycodone Sandoz.

4. How do I use Oxycodone Sandoz?

How much to take

- Your doctor will tell you how much to take.
- Follow the instructions provided and use Oxycodone Sandoz until your doctor tells you to stop.

When to take Oxycodone Sandoz

- Oxycodone Sandoz should be taken every 12 hours.
- Take Oxycodone Sandoz regularly to control the pain.

Taking them at the same time each day will assist in ensuring the best effect in improving your pain. If however, you begin to experience worsening pain and you are taking your Oxycodone Sandoz as prescribed, contact your doctor as your dosage may have to be reviewed.

How to take Oxycodone Sandoz

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

Oxycodone Sandoz 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, which can be dangerous and cause serious problems, such as an overdose, which may be fatal.

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

You must only take Oxycodone Sandoz by the mouth.

If you forget to use Oxycodone Sandoz

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

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

- This will increase the chance of you getting unwanted side effects.
- If you have trouble remembering when to take your medicine, ask your pharmacist for hints.
- For example, take your medicine at the same time each morning and evening such as 8 a.m. and 8 p.m.

If you use too much Oxycodone Sandoz

If you or someone else receive too much (overdose), and experience one or more of the symptoms below, call triple zero (000) in Australia or triple one (111) in New Zealand 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 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 or fits.

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

- phone the Australian Poisons Information Centre (**by calling 13 11 26**), or the New Zealand National Poisons Information Centre (**by calling 0800 POISONS or 0800 764766**), 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 remaining medicine with you to show the doctor. Also tell them about any other medicines or alcohol which have been taken.

5. What should I know while using Oxycodone Sandoz?

Things you should do

- Take Oxycodone Sandoz exactly as your doctor has prescribed.

- Before you start on a new medicine, remind your doctor and pharmacist that you are taking Oxycodone Sandoz.
- Keep all of your doctor's appointments so that your progress can be checked.

Call your doctor straight away if you:

- become pregnant
- feel your pain is getting worse.

Remind any doctor, dentist or pharmacist you visit that you are using Oxycodone Sandoz.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

Things you should not do

- Do not stop using this medicine suddenly, exceed the dose recommended or change the dosage without checking with your doctor. Over time your body may become used to oxycodone. If you stop taking it suddenly, your pain may worsen and you may experience 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 take Oxycodone Sandoz to treat any other complaint unless your doctor tells you to.
- Do not give this medicine to anyone else, even if they have the same condition as you.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Oxycodone Sandoz affects you.

Oxycodone Sandoz may cause drowsiness, dizziness, hallucinations, disorientation, blurred vision or other vision problems or may affect alertness. If you are affected, you should not drive or operate machinery. Discuss these effects with your doctor.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may make you feel more sleepy, and could increase the risk of serious side effects, such as shallow breathing with the risk of stopping breathing and loss of consciousness.

Looking after your medicine

- Keep your tablets in the blister pack until it is time to take them.
- If you take the tablets out of the blister pack they may not keep as well.
- Keep your tablets in a cool, dry place, where the temperature stays below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or

- in the car or on window sills.

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.

Getting rid of any unwanted medicine

If the medicine is damaged, you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Mouth, gastrointestinal and urinary related:</p> <ul style="list-style-type: none"> • mild abdominal problems such as diarrhoea, feeling sick (nausea), decreased appetite or constipation • dry mouth, hiccups, sore throat, or changes in voice <p>Endocrine related:</p> <ul style="list-style-type: none"> • problems with your adrenal glands including nausea, vomiting, anorexia, fatigue, weakness, dizziness, or low blood pressure <p>General body related:</p> <ul style="list-style-type: none"> • excessive sweating • skin rash, itching, chills or fever <p>Neurological and behaviour related:</p> <ul style="list-style-type: none"> • feeling anxious or nervous, trouble sleeping or abnormal dreams • trouble with your balance <p>Eye related:</p> <ul style="list-style-type: none"> • new problems with your eyesight <p>Muscle and limb related:</p> <ul style="list-style-type: none"> • muscle problems such as spasms, twitching or tremors • swelling of legs or ankles 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Reproductive related: <ul style="list-style-type: none"> absence of menstrual periods impotence decreased sexual drive. 	
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Serious side effects

Serious side effects	What to do
Mouth, gastrointestinal and urinary related: <ul style="list-style-type: none"> stomach discomfort, vomiting, indigestion or abdominal pain choking, gagging, regurgitation, tablets stuck in throat or trouble swallowing the tablets changes in passing urine such as the volume passed, pain or feeling the need to urinate urgently inflammation of the pancreas Neurological and behaviour related: <ul style="list-style-type: none"> abnormal thinking, changes in mood or feeling deep sadness drowsiness, feeling faint or fainting, or dizziness especially when standing up headache or confusion fatigue, feeling of tiredness, drowsiness or lack of energy seizures, fits or convulsions Heart and lung related: <ul style="list-style-type: none"> slow or noticeable heartbeats your breathing slows or weakens fast or irregular heartbeats chest pain or chest tightness. Muscle and limb related: <ul style="list-style-type: none"> unusual weakness, loss of strength or trouble walking Allergic reaction related: <ul style="list-style-type: none"> 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. 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

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

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems or to Medsafe at <https://pophealth.my.site.com/carmreportnz/s/>. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Oxycodone Sandoz contains

Active ingredient (main ingredient)	oxycodone hydrochloride
Other ingredients (inactive ingredients)	Excipients core: <ul style="list-style-type: none"> maize starch behenoyl polyoxyglycerides lactose monohydrate medium chain triglycerides copovidone castor oil – hydrogenated colloidal anhydrous silica magnesium stearate Excipients coating: <ul style="list-style-type: none"> hypromellose microcrystalline cellulose stearic acid titanium dioxide indigo carmine aluminium lake (5 mg tablets only) 815063 Spectracol Green Lake (80 mg tablets only) iron oxide red (20 mg tablets only) iron oxide yellow (40 mg tablets only) iron oxide black (80 mg tablets only)
Potential allergens	lactose

Do not take this medicine if you are allergic to any of these ingredients.

What Oxycodone Sandoz looks like

Oxycodone Sandoz comes in five strengths:

Oxycodone Sandoz 5 mg - blue, round, biconvex modified release tablets (Aust R 153605).

Oxycodone Sandoz 10 mg - white, round, biconvex modified release tablets (Aust R 153597).

Oxycodone Sandoz 20 mg - pink, round, biconvex modified release tablets (Aust R 153615).

Oxycodone Sandoz 40 mg - yellow, round, biconvex modified release tablets (Aust R 153611).

Oxycodone Sandoz 80 mg - green, round, biconvex modified release tablets (Aust R 153591).

Available in blister packs of 20, 28 and 60 tablets.

Not all pack sizes may be available in Australia and New Zealand.

Who distributes Oxycodone Sandoz

Oxycodone Sandoz is distributed in Australia by:

Sandoz Pty Ltd
100 Pacific Highway
North Sydney, NSW 2060
Australia
Tel 1800 726 369

Oxycodone Sandoz is distributed in New Zealand by:

Sandoz New Zealand Limited
12 Madden Street
Auckland 1010
New Zealand
Tel: 0800 726 369

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