

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 hydrochloride solution for injection or infusion?

Oxycodone hydrochloride solution for injection or infusion contains the active ingredient oxycodone hydrochloride. Oxycodone hydrochloride solution for injection or infusion is used to relieve short-term management of severe pain.

For more information, see Section [1. Why am I using Oxycodone hydrochloride solution for injection or infusion?](#) in the full CMI.

2. What should I know before I use Oxycodone hydrochloride solution for injection or infusion?

Do not use if you have ever had an allergic reaction to oxycodone hydrochloride, opioid painkillers 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 hydrochloride solution for injection or infusion?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Oxycodone hydrochloride solution for injection or infusion 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 hydrochloride solution for injection or infusion?

- Your doctor will decide the appropriate dose for you.
- Oxycodone hydrochloride injection or infusion can be given as a single injection or infusion into a vein or can also be administered through a fine needle into the tissue under the skin.

More instructions can be found in Section [4. How do I use Oxycodone hydrochloride solution for injection or infusion?](#) in the full CMI.

5. What should I know while using Oxycodone hydrochloride solution for injection or infusion?

Things you should do	<ul style="list-style-type: none"> Remind any doctor, dentist or pharmacist you visit that you are using this medicine.
Things you should not do	<ul style="list-style-type: none"> Do not stop using this medicine suddenly exceed the dose recommended or change the dosage without checking with your doctor.
Driving or using machines	<ul style="list-style-type: none"> Do not drive or operate machinery until you know how oxycodone hydrochloride injection or infusion affects you.
Drinking alcohol	<ul style="list-style-type: none"> Do not drink alcohol while you are being given this medicine.
Looking after your medicine	<ul style="list-style-type: none"> Product is for single use in one patient only. keep the unopened ampoules in a cool, dry place where the temperature stays below 25°C at home or in the pharmacy or on the ward.

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

6. Are there any side effects?

Tell your doctor as soon as possible if you do not feel well while you are having Oxycodone hydrochloride injection or infusion.

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 hydrochloride solution for injection or infusion 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 hydrochloride solution for injection or infusion 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 hydrochloride solution for injection or infusion 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 hydrochloride solution for injection or infusion 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 hydrochloride solution for injection or infusion

Using Oxycodone hydrochloride solution for injection or infusion 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 Oxycodone hydrochloride solution for injection or infusion.

OXYCODONE HCl

Active ingredient(s): Oxycodone hydrochloride (*ox-ee-code-own hi-dro-klor-ide*)

Consumer Medicine Information (CMI)

This leaflet provides important information about using Oxycodone hydrochloride solution for injection or infusion. **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 hydrochloride solution for injection or infusion.**

Where to find information in this leaflet:

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

1. Why am I using Oxycodone hydrochloride solution for injection or infusion?

Oxycodone hydrochloride solution for injection or infusion contains the active ingredient oxycodone hydrochloride. Oxycodone hydrochloride solution for injection or infusion is opioid analgesics.

Oxycodone hydrochloride solution for injection or infusion is used to relieve short-term management of severe pain for which other treatment options have failed or are otherwise inappropriate to provide sufficient management of pain. It can be given as a single injection or as an infusion into a vein or into the tissue under the skin. 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 having oxycodone. Being given it may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop having oxycodone suddenly, so it is important that you are given Oxycodone hydrochloride solution for injection or infusion exactly as directed by your doctor.

2. What should I know before I use Oxycodone hydrochloride solution for injection or infusion?

Warnings

Do not use Oxycodone hydrochloride solution for injection or infusion if:

- you are allergic to oxycodone, opioid painkillers, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions
 - have any breathing problems such as acute asthma, respiratory depression (breathing slows or weakens) or other obstructive airways disease
 - 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 disease due to long-term lung disease
 - have just consumed a large amount of alcohol, regularly consume large amounts of alcohol or have confusion and shaking due to alcohol withdrawal
 - suffer anxiety from taking hypnotics, medicines that are given to help people sleep
 - suffer from convulsions, fits or seizures
 - have a head injury, brain tumour, or have raised pressure within the head, brain or spinal cord
 - have sudden, severe abdominal pain or chronic constipation
 - have a condition where your stomach empties more slowly than it should, or your small bowel does not work properly
 - have severe kidney disease
 - have moderate to severe liver disease
 - are about to have surgery on your spine for pain relief in the next 6 hours
- have or have had any other medical conditions
 - Have 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
 - you have had recent abdominal surgery, you are about to have surgery or you have had surgery within the last 24 hours
 - 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.
- take any medicines for depression called a 'monoamine oxidase inhibitor' or have taken any in the last two weeks.
- Have allergies to any other medicines, foods, preservatives or dyes. 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

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 used during labour.

Oxycodone given to the mother during labour can 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 breast milk and can affect the baby. Your doctor can discuss the risks involved.

If you have not told your doctor about any of the above, tell them before you have Oxycodone hydrochloride injection or infusion.

You should not be given this medicine if you are pregnant or intend to become pregnant.

Like most medicines of this kind, Oxycodone hydrochloride injection or infusion is not recommended to be given during pregnancy. Your doctor will discuss the risks of having it if you are pregnant.

Other conditions when not to take this medicine

- You should not be given this medicine if you are 18 years of age or younger. Safety and effectiveness in children younger than 18 years of age have not been established.
- You should not continue to have Oxycodone hydrochloride infusion 50 mg in 1 mL if you have been given Oxycodone hydrochloride infusion 50 mg in 1 mL for more than 4 consecutive weeks.

Addiction

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

Tolerance

Tolerance to Oxycodone hydrochloride injection or infusion 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 hydrochloride solution for injection or infusion and affect how it works.

- 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 hydrochloride injection or infusion is given
- antidepressants e.g. citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, venlafaxine.
- 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,
- 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
- antibiotics, e.g. clarithromycin erythromycin, rifampicin
- medicines to treat fungal infections e.g. ketoconazole
- alcohol
- medicine to treat HIV infection and AIDS e.g. ritonavir
- 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 hydrochloride injection or infusion, may affect how well Oxycodone hydrochloride injection or infusion works or may increase side effects. You may need to use different amounts of the 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 hydrochloride solution for injection or infusion.

4. How do I use Oxycodone hydrochloride solution for injection or infusion?

How much to take / use

- Your doctor will decide the appropriate dose for you.
- **You should not be given Oxycodone hydrochloride infusion 50 mg in 1 mL for more than 4 consecutive weeks.**
- Follow the instructions provided and use Oxycodone hydrochloride solution for injection or infusion until your doctor tells you to stop.

When to take / use Oxycodone hydrochloride solution for injection or infusion

- Oxycodone hydrochloride solution for injection or infusion should be used as directed by your doctor.
- If you begin to experience pain, tell your doctor as your dosage may have to be reviewed.

How to take/ use Oxycodone hydrochloride solution for injection or infusion

- A doctor or nurse will usually prepare and administer Oxycodone hydrochloride injection or infusion.
- **Oxycodone hydrochloride injection or infusion 10 mg in 1 mL or 20 mg in 2 mL can be given as a single injection or infusion into a vein. It can also be administered through a fine needle into the tissue under the skin.**
- **Oxycodone hydrochloride infusion 50 mg in 1 mL can only be given as an infusion into a vein or an infusion into the tissue under the skin.**
- Your doctor will decide the most appropriate way to administer Oxycodone hydrochloride injection or infusion. Using this medicine in a manner other than that prescribed by your doctor can be harmful to your health.

If you use too much Oxycodone hydrochloride solution for injection or infusion

If you or someone else receive too much (overdose), and experience one or more of the 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 hydrochloride injection or infusion 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 have used too much Oxycodone hydrochloride solution for injection or infusion, you may need urgent medical attention.

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 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 hydrochloride solution for injection or infusion?

Things you should do

Call your doctor straight away if:

- You become pregnant while being given this medicine, tell your doctor immediately.
- your pain is getting worse. Always discuss any problems or difficulties you have while you are being treated with Oxycodone hydrochloride injection or infusion.

Remind any doctor, dentist or pharmacist you visit that you are using Oxycodone hydrochloride solution for injection or infusion.

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

It may affect other medicines used during surgery.

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

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

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.

If you stop having this medicine suddenly, the 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 need to stop having this medicine, your doctor will gradually reduce the amount each day, if possible, before stopping the medicine completely.

- **Do not use Oxycodone hydrochloride injection or infusion to treat any other complaint unless your doctor tells you to.**
- **Do not give the medicine to anyone else, even if they have the same condition as you.**

Things to be careful of

- **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 having Oxycodone hydrochloride injection or infusion.**
Your doctor may prescribe some medicine to help you stop vomiting.
- **Tell your doctor if having Oxycodone hydrochloride injection or infusion 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.
- **Tell your doctor if you find that you cannot concentrate or that you feel more sleepy than normal when you are being treated with Oxycodone hydrochloride injection or infusion or when the dose is increased.**
This feeling should wear off after a few days.
- **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.**

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Oxycodone hydrochloride solution for injection or infusion affects you.

Oxycodone hydrochloride injection or infusion 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 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

- Product is for single use in one patient only.
- If you are being given Oxycodone hydrochloride injection or infusion in hospital, unopened ampoules will be stored in the pharmacy or on the ward.
- If you have some of this medicine at home, keep the unopened ampoules 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 meters above the ground is a good place to store medicines.

When to discard your medicine (as relevant)

- Oxycodone hydrochloride injection or infusion should be given immediately after opening the ampoule. Once opened, any unused portion should be discarded.
- Do not use this medicine if the packaging is torn or shows signs of tampering or if the injection shows any visible signs of deterioration.

Getting rid of any unwanted medicine

If 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.

If you are given it after the expiry date has passed, it may not work very well.

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.

As for many 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 have 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 this list of possible side effects.

Not everybody experiences them.

This medicine helps most people with moderate to severe pain, but it may have unwanted side effects in a few people.

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
<ul style="list-style-type: none"> • mild abdominal symptoms such as diarrhoea, feeling sick (nausea), decreased appetite, constipation or excessive wind • dry mouth, hiccups or trouble swallowing • excessive sweating • feeling anxious or nervous or have trouble sleeping • trouble with your balance (vertigo) • looking pale or feeling excessively tired • new problems with your eyesight • skin rash, itching, chills or fever • unusually reduced or slow body movements • muscle problems such as spasms, twitching or tremors • swelling of legs or ankles • pain and sensitivity at the injection site • absence of menstrual periods • erectile dysfunction • decreased sexual drive. 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • 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, confusion, hallucinations, disorientation, sleepiness or impaired consciousness • unusual weakness or loss of strength • 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 or difficulty passing urine 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> <p>It may require medical treatment.</p>

Very serious side effects

Very serious side effects	What to do
<ul style="list-style-type: none">• 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.	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.

When seeking medical attention take this leaflet and any remaining medicine with you to show the doctor.

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. 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 hydrochloride solution for injection or infusion contains

Active ingredient (main ingredient)	oxycodone hydrochloride
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• citric acid monohydrate• sodium citrate dihydrate• sodium chloride• hydrochloric acid• sodium hydroxide• water for injections.
Potential allergens	None

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

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

What Oxycodone hydrochloride solution for injection or infusion looks like

Oxycodone hydrochloride solution for injection or infusion is available in glass ampoules containing a clear, colourless or yellowish solution. It is available in two presentations:

10 mg/1 mL: AUST R 323828

20 mg/2 mL: AUST R 323826

Oxycodone hydrochloride solution for infusion is available in glass ampoules containing a clear, colourless or yellowish solution. It is available in one presentation:

50 mg/1 mL: AUST R 323824

Oxycodone hydrochloride solution for injection or infusion and Oxycodone hydrochloride solution for infusion are supplied in packs of 5 and 10 ampoules.

Not all presentations and pack sizes are marketed.

Who distributes Oxycodone hydrochloride solution for injection or infusion

Marketed and distributed by Medsurge Healthcare Pty Ltd

Unit 1&2, 6-7 Gilda Court

MULGRAVE, VICT. 3170

Tel: 1300 788 261

www.medsurgehc.com

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