

OXYCODONE HCl

Oxycodone hydrochloride

Consumer Medicine Information

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.

What is in this leaflet

This leaflet answers some common questions about Oxycodone hydrochloride solution for injection or infusion ("injection or infusion").

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up-to-date information on the medicine.

Those updates may contain important information about the medicine and its use which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given this

medicine against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, talk to your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What Oxycodone hydrochloride injection or infusion is given for

Oxycodone hydrochloride solution for injection or infusion contains oxycodone hydrochloride.

Oxycodone belongs to a group of medicines called opioid analgesics.

Oxycodone hydrochloride injection or infusion is given 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 this medicine has been prescribed for you.

As with all strong painkillers, your body may become used to you having oxycodone. Being given this medicine 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 injection or infusion exactly as directed by your OXYCODONE HCl Oxycodone hydrochloride doctor.

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

Before you are given Oxycodone hydrochloride injection or infusion

Long term use of Oxycodone hydrochloride injection or solution may result in a decrease in sex hormone levels which may affect sperm production in men and the menstrual cycle in females.

Talk to your doctor if you have any concerns.

When you must not have this medicine

You should not have Oxycodone hydrochloride injection or infusion if you are allergic to oxycodone, opioid painkillers, or any of the ingredients listed at the end of this leaflet.

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

You should not be given Oxycodone hydrochloride injection or infusion if you:

- 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
- take a medicine for depression called a 'monoamine oxidase inhibitor' or have taken any in the last two weeks.

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.

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 this medicine if you are pregnant.

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.

Do not use this medicine after the expiry date (EXP) printed on the pack.

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

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.

Before you start to have this medicine

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 medical conditions, especially the following:

- 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.

Pregnancy and breastfeeding.

This medicine is not recommended to be used during labour.

Oxycodone hydrochloride injection or infusion given to the mother during labour can cause breathing problems and signs of withdrawal in the newborn.

Tell your doctor if you are currently breastfeeding or you plan to breast-feed.

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.

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.

Taking other medicines

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

Some medicines, dietary supplements and Oxycodone hydrochloride injection or infusion may interfere with each other. These include:

- medicines to treat depression, psychiatric or mental disorders
- medicines to treat depression belonging to a group called monoamine oxidase inhibitors 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.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while using this medicine.

How Oxycodone hydrochloride injection or infusion is given

How much medicine is given

Your doctor will decide the appropriate dose for you.

How this medicine is given

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.

When this medicine is given

You should be given Oxycodone injection or infusion as directed by your doctor.

If you begin to experience pain, tell your doctor as your dosage may have to be reviewed.

How long is this medicine given for

You should be given this medicine for as long as directed by your doctor.

You should not be given Oxycodone hydrochloride infusion 50 mg in 1 mL for more than 4 consecutive weeks.

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 diarrhea
- fast heart rate
- sneezing or runny nose
- chills, tremors, shivering or fever
- trouble sleeping
- increased sweating and yawning
- weakness
- nervousness or restlessness.

If you are given too much (overdose)

If you or someone else receive too much (overdose), and experience one or more of the symptoms below, immediately remove the patch(es) and 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 above steps even if someone other than you have accidentally used Oxycodone hydrochloride solution for 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 you or someone else may have used too much Oxycodone hydrochloride solution for injection or infusion, 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.

While you are given Oxycodone hydrochloride injection or infusion

Things you must do

Before you start on a new medicine, remind your doctor and pharmacist that you are being given Oxycodone hydrochloride injection or infusion.

Tell any other doctors, dentists and pharmacists who treat you that you are having this medicine.

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.

If you become pregnant while being given this medicine, tell your doctor immediately.

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

Tell your doctor if your pain is getting worse.

Always discuss any problems or difficulties you have while you are being treated with Oxycodone hydrochloride injection or infusion.

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 must not do

Do not drink alcohol while you are being given this medicine.

Drinking alcohol whilst using Oxycodone hydrochloride injection or infusion 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 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.

Oxycodone hydrochloride injection or infusion is intended for use in one patient only.

Do not stop using the medicine, exceed the dose recommended or change the dosage without checking with your doctor.

Over time your body may become used to oxycodone so if it is stopped

suddenly, the pain may worsen, and you may have unwanted side effects such as withdrawal symptoms. This is called physical dependence.

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

Things to be careful of

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

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
OXYCODONE HCl 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.

Side effects

All medicines may have some unwanted side effects. Sometimes they are serious but most of the time they are not. 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.

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

This medicine helps most people with moderate to severe pain, but it may have unwanted side effects in a few people. Other side effects not listed here may also occur in some people.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- 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.

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

- stomach discomfort, vomiting, indigestion or abdominal pain
- abnormal thinking, changes in mood or feeling deep sadness
- drowsiness, fainting or dizziness especially when standing up
- slow or noticeable heartbeats
- headache, 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.

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 the 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 hospitalization.

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

After having it

Storage

Oxycodone hydrochloride injection or infusion should be given immediately after opening the ampoule. Once opened, any unused portion should be discarded. 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.

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

Do not leave it in the car.

Heat and damp 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 having this medicine or the medicine has passed the expiry date, ask your pharmacist how to dispose of medicines no longer required.

Product description

What it 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 in 1 mL
- 20 mg in 2 mL.

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 in 1 mL.

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.

Ingredients

Active ingredient:

1 mL of Oxycodone hydrochloride solution for injection or infusion 10 mg in 1 mL and 20 mg in 2 mL both contain 10 mg of oxycodone hydrochloride.

1 mL of Oxycodone hydrochloride solution for infusion 50 mg in 1 mL contain 50 mg of oxycodone hydrochloride.

Inactive ingredients:

- citric acid monohydrate
- sodium citrate dihydrate
- sodium chloride
- hydrochloric acid
- sodium hydroxide

- water for injections.

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

Manufacturer / Sponsor

Australian Sponsor

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Marketed and distributed by Medsurge Healthcare Pty Ltd

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Registration Numbers:

Oxycodone hydrochloride solution for injection or infusion are:

10 mg/1 mL: AUST R 323828

20 mg/2 mL: AUST R 323826

Oxycodone hydrochloride solution for infusion is:

50 mg/1 mL: AUST R 323824

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