

Oxycodone-hameln Solution for Injection or Infusion

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 being given Oxycodone-hameln?

Oxycodone-hameln contains the active ingredient oxycodone hydrochloride. Oxycodone-hameln 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.

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

2. What should I know before I am given Oxycodone-hameln?

Do not use if you have ever had an allergic reaction to oxycodone 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 am given Oxycodone-hameln?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Oxycodone-hameln 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 is Oxycodone-hameln given?

- Your doctor will tell you exactly how much to take.
- Follow the instructions given to you by your doctor or your pharmacist.

More instructions can be found in Section [4. How will I be given Oxycodone-hameln?](#) in the full CMI.

5. What should I know while I am being given Oxycodone-hameln?

Things you should do	<ul style="list-style-type: none">• Remind any doctor or dentist you visit that you are using Oxycodone-hameln.• 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.
Driving or using machines	<ul style="list-style-type: none">• Oxycodone-hameln 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 30°C.• Oxycodone-hameln injection or infusion should be given immediately after opening the ampoule. Once opened, any unused portion should be discarded.• Do not store oxycodone or any other medicine in the bathroom or near a sink. Do not leave it on a windowsill or in the car. Keep it where young children cannot reach it.

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

6. Are there any side effects?

Oxycodone-hameln 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-hameln 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-hameln 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-hameln 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-hameln 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-hameln

Using Oxycodone-hameln with other medicines that can make you feel drowsy such as sleeping (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-hameln.

Oxycodone-hameln

Active ingredient: *oxycodone hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Oxycodone-hameln. **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-hameln.**

Where to find information in this leaflet:

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

1. Why am I being given Oxycodone-hameln?

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

Oxycodone-hameln 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.

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

2. What should I know before I am given Oxycodone-hameln?

Warnings

Long-term use of Oxycodone-hameln 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.

Do not use Oxycodone-hameln if you:

- are allergic to oxycodone hydrochloride, 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.
- 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-hameln infusion 50 mg in 1 mL if you have been given Oxycodone-hameln infusion 50 mg in 1 mL for more than 4 consecutive weeks.

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.

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes
- 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

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

Tolerance

Tolerance to Oxycodone-hameln 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-hameln 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-hameln 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-hameln, may affect how well Oxycodone-hameln 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-hameln .

4. How is Oxycodone-hameln given?

How much is given

Your doctor will decide the appropriate dose for you.

When is Oxycodone-hameln given

You should be given Oxycodone-hameln 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 is Oxycodone-hameln given?

A doctor or nurse will usually prepare and administer Oxycodone-hameln injection or infusion.

Oxycodone-hameln 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-hameln 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 and should not be given for more than 4 consecutive weeks.

Your doctor will decide the most appropriate way to administer Oxycodone-hameln injection or infusion. Using this medicine in a manner other than that prescribed by your doctor can be harmful to your health.

If you are given too much Oxycodone-hameln (overdose)

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 above steps even if someone other than you have accidentally used Oxycodone-hameln 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-hameln 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 I am being given Oxycodone-hameln?

Things you should do

- Before you start on a new medicine, remind your doctor and pharmacist that you are taking Oxycodone-hameln.
- 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 or dentist or pharmacist you visit that you are using Oxycodone-hameln.

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

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-hameln injection or infusion.

Your doctor may prescribe some medicine to help you stop vomiting.

Tell your doctor if having Oxycodone-hameln 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-hameln injection or infusion or when the dose is increased.

This feeling should wear off after a few days.

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-hameln 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.

Oxycodone-hameln is intended for use in one patient only.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Oxycodone-hameln affect you.

Oxycodone-hameln 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.

Drinking alcohol while using Oxycodone-hameln may make you feel sleepier, 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

- Oxycodone-hameln injection or infusion should be given immediately after opening the ampoule. Once opened, any unused portion should be discarded.
- If you are being given Oxycodone-hameln 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 and protected from light.

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
Gastrointestinal and urinary related: <ul style="list-style-type: none">• mild abdominal problems such as diarrhoea, feeling sick (nausea), decreased appetite or constipation or excessive wind• dry mouth, hiccups or trouble swallowing• excessive sweating• feeling anxious or nervous or have trouble sleeping	Speak to your doctor if you have any of these less serious side effects and they worry you.

<ul style="list-style-type: none"> • 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. 	
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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>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.</p>

The following list includes very serious side effects; you may need urgent medical attention or hospitalisation. 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.

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. 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-hameln 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	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-hameln looks like

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

- 10 mg in 1 mL (AUST R 343480)
- 20 mg in 2 mL (AUST R 343479)

Oxycodone-hameln solution for infusion is available in glass ampoules containing a clear, colourless solution. It is available in one presentation:

- 50 mg in 1 mL (AUST R 343481)

Oxycodone-hameln is supplied in packs of 5 or 10 ampoules.

Who distributes Oxycodone-hameln

hameln pharma Pty Ltd
Level 3, 302 Burwood Rd,
Hawthorn, Victoria 3122,
Australia

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