

Oxycodone Juno 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 Juno?

Oxycodone Juno contains the active ingredient oxycodone hydrochloride. Oxycodone Juno is used for the short-term relief of severe pain for which other treatment options have failed or otherwise unsuitable to provide sufficient management of pain. For more information, see [Section 1. Why am I being given Oxycodone Juno?](#) in the full CMI.

2. What should I know before I am given Oxycodone Juno?

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. **A number of medical conditions and other drugs can affect the way Oxycodone Juno works and may result in side-effects. Prior to being treated with Oxycodone Juno, 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 Juno?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Oxycodone Juno 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 will I be given Oxycodone Juno?

- Your doctor will decide the appropriate dose for you.
- Follow the instructions given to you by your doctor or pharmacist exactly.
- Oxycodone Juno must only be administered by injection, and will normally be given to you by a doctor or nurse.

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

5. What should I know while using Oxycodone Juno?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Oxycodone Juno• Tell your doctor or pharmacist if you are taking any other medicines that you use to help you relax, anything that contains alcohol (like cough syrup) or other medicines that treat pain• Tell your doctor if your pain is getting worse, or the effect of the medicine seems to decrease.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine, exceed the dose recommended, or change the dosage without checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">• Oxycodone Juno may cause drowsiness, dizziness, hallucinations, disorientation, blurred vision and affect alertness. If affected do not drive a vehicle or operate machinery.
Drinking alcohol	<ul style="list-style-type: none">• Do not drink alcohol while being given Oxycodone Juno• Do not take Oxycodone Juno if you have just consumed a large amount of alcohol, regularly consume large amounts of alcohol or have confusion and shaking due to alcohol withdrawal.
Looking after your medicine	<ul style="list-style-type: none">• Store below 30°C, protected from light• Keep it where young children cannot reach it.

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

6. Are there any side effects?

Oxycodone Juno Injection may cause constipation, nausea, 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.

Oxycodone Juno Injection

Active ingredient(s): *Oxycodone Hydrochloride*

WARNING:

Limitations of use

Oxycodone Juno 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 Juno 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 Juno 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 Juno 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 Juno

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

Consumer Medicine Information (CMI)

This leaflet provides important information about using Oxycodone Juno. **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 Juno.**

Where to find information in this leaflet:

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

1. Why am I being given Oxycodone Juno?

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

Oxycodone Juno is given for the short-term relief of severe pain for which other treatment options have failed or otherwise unsuitable 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 have prescribed it for another purpose.

2. What should I know before I am given Oxycodone Juno?

Long-term use of Oxycodone Juno may result in a decrease of 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 Juno 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
- 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
- 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 Juno infusion 50 mg in 1 mL if you have been given Oxycodone Juno 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.

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.

Check with your doctor if you:

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

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

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.

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 Juno 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 Juno injection or infusion is not recommended to be given during pregnancy. Your doctor will discuss the risks of having it if you are pregnant.

Addiction

You can become addicted to Oxycodone Juno even if you take it exactly as prescribed. Oxycodone Juno may become habit forming causing mental and physical dependence. If abused it may become less able to reduce pain.

It is important that you discuss this issue with your doctor.

Dependence

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

Tolerance

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

If this happens, your doctor may review the dose so that you get adequate pain relief.

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 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 Juno 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 Juno 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 Juno injection or infusion, may affect how well Oxycodone Juno 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.

4 How will I be given Oxycodone Juno?

How much will be given

Your doctor will decide the appropriate dose for you.

When will I be given Oxycodone Juno

You should be given Oxycodone Juno 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 will Oxycodone Juno be given for

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

You should not be given Oxycodone Juno 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 diarrhoea

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

How you will be given Oxycodone Juno

A doctor or nurse will usually prepare and administer the injection or infusion.

Oxycodone Juno 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 Juno 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 for you to have Oxycodone Juno. 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 Juno

Immediately telephone your doctor, or the Poisons Information Centre (Australia: telephone 13 11 26) for advice or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have been given too much Oxycodone Juno injection or infusion.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Keep telephone numbers for these places handy.

Symptoms of an overdose may include: difficulties in breathing, become drowsy and tired, lack muscle tone, have cold or clammy skin, have constricted pupils, have very low blood pressure or slow heart rate, and possibly may even become unconscious or die.

When seeking medical attention, take this leaflet, any remaining medicine or the empty ampoule if you still have it with you to show your doctor. Also tell them about any other medicines or alcohol which have been taken.

5. What should I know while being given Oxycodone Juno?

Things you must do

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

Things you must not do

Do not use Oxycodone Juno 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 Juno 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

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 Juno injection or infusion. Your doctor may prescribe some medicine to help you stop vomiting.

Tell your doctor if having Oxycodone Juno 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 Juno 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

Do not drive or operate machinery until you know how Oxycodone Juno injection or infusion affects you.

Oxycodone Juno 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

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

Drinking alcohol whilst using Oxycodone Juno 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.

Looking after your medicine

Oxycodone Juno 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 Juno 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 30°C and protected from light.

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.

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.

6. Are there any 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 Juno 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.

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.	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

The following list includes serious side effects that may require medical attention.

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	Call your doctor straight away, or go straight to the Emergency Department at your

<ul style="list-style-type: none"> 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. 	nearest hospital if you notice any of these serious side effects.
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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.

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

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 Juno contains

Active ingredient (main ingredient)	oxycodone hydrochloride
Other ingredients (inactive ingredients)	citric acid monohydrate sodium citrate sodium chloride hydrochloric acid sodium hydroxide water for injections

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

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

What Oxycodone Juno looks like

Oxycodone Juno 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
- 20 mg in 2 mL

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

- 50 mg in 1 mL

Oxycodone Juno solution for injection or infusion and Oxycodone Juno solution for infusion are supplied in packs of 4* or 5 ampoules.

10 mg/1 mL ARTG ID : '279321'

20 mg/2 mL ARTG ID : '279323'

50 mg/1 mL ARTG ID : '279328'

200 mg/20 mL* ARTG ID : '279325'

Not all presentations may be marketed.

Who distributes Oxycodone Juno

Juno Pharmaceuticals Pty Ltd
42 Kelso Street, Cremorne,
Victoria 3121,
Australia

This leaflet was prepared in October 2023.