

HYDROMORPHONE JUNO/HYDROMORPHONE JUNO-HP/ HYDROMORPHONE JUNO-XHP

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 HYDROMORPHONE JUNO/JUNO-HP/JUNO-XHP?

HYDROMORPHONE JUNO/JUNO-HP/JUNO-XHP contain the active ingredient hydromorphone hydrochloride. Hydromorphone 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 using HYDROMORPHONE?](#) in the full CMI.

2. What should I know before I use HYDROMORPHONE JUNO/JUNO-HP/JUNO-XHP?

Do not use if you have ever had an allergic reaction to hydromorphone 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 HYDROMORPHONE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with hydromorphone 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 HYDROMORPHONE JUNO/JUNO-HP/JUNO-XHP?

- Your doctor will decide the appropriate dose for you.
- A doctor or nurse will usually prepare and administer the injection or infusion.
- Follow all instructions given to you by your doctor and pharmacist.

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

5. What should I know while using HYDROMORPHONE JUNO/JUNO-HP/JUNO-XHP?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are receiving hydromorphone.• Tell your doctor or pharmacist if you are taking/using any other medicines/substances that can make you feel drowsy.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly unless your doctor tells you to.• Do not use more than your doctor tells you to.
Driving or using machines	<ul style="list-style-type: none">• Hydromorphone may cause drowsiness. If affected do not drive or operate machinery.
Drinking alcohol	<ul style="list-style-type: none">• Avoid alcohol. Alcohol may make you feel more sleepy and could increase the risk of serious side effects, such as shallow breathing with the risk of stopping breathing and loss of consciousness.
Looking after your medicine	<ul style="list-style-type: none">• Store below 25°C. Protect from light.• Keep it where young children cannot reach it.

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

6. Are there any side effects?

Hydromorphone injections may cause constipation, nausea, dizziness, drowsiness and be habit forming if used frequently 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: Hydromorphone 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: Hydromorphone poses risks of abuse, misuse and addiction which can lead to overdose and death. Your doctor will assess any risks before prescribing this medicine and will monitor you regularly during treatment.

Life threatening respiratory depression: Hydromorphone can cause serious, 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 greatest when starting treatment or following an increase in dose. The risk is higher in elderly, frail or debilitated patients, as well as those with kidney or liver impairment or existing lung/airway conditions. Your doctor will monitor you and change the dose as appropriate.

Use of other medicines: Using hydromorphone with other medicines/substances that make you drowsy, such as sleeping/anti-anxiety tablets (benzodiazepines), other pain relievers, antihistamines, antidepressants, antipsychotics, gabapentinoids (e.g. gabapentin and pregabalin), cannabis and alcohol may cause severe drowsiness, decreased awareness, breathing problems, coma and death. Your doctor will minimize the dose and duration of use and will monitor you for any signs and symptoms of breathing difficulties and sedation. You must not drink alcohol while being treated with hydromorphone.

HYDROMORPHONE JUNO/HYDROMORPHONE JUNO-HP/ HYDROMORPHONE JUNO-XHP

Active ingredient(s): Hydromorphone hydrochloride (*hi-dro-morf-own hi-dro-klor-ide*)

Consumer Medicine Information (CMI)

This leaflet provides important information about using hydromorphone. **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 this medicine.**

Where to find information in this leaflet:

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

1. Why am I using HYDROMORPHONE JUNO/JUNO-HP/JUNO-XHP?

HYDROMORPHONE JUNO/JUNO-HP/JUNO-XHP contains the active ingredient hydromorphone hydrochloride.

Hydromorphone belongs to a group of medicines called opioid analgesics.

Hydromorphone is used to provide short term management of severe pain for which other treatment

options have failed or are otherwise inappropriate to provide sufficient management of pain.

2. What should I know before I use HYDROMORPHONE JUNO/JUNO-HP/JUNO-XHP?

Warnings

Do not use HYDROMORPHONE JUNO/JUNO-HP/JUNO-XHP if:

- You are allergic to hydromorphone, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- You suffer from shallow or difficult breathing or have any severe or acute breathing problems such as acute asthma or bronchitis.
- You have severe abdominal pain with bloating, cramps or vomiting.
- You have a condition where your small bowel does not work properly.
- You take medicine for depression called a 'monoamine oxidase inhibitor' or have taken any in the last two weeks.
- You are pregnant or in labour.

Check with your doctor if you:

- Take any medicines for any other condition.
- Are severely drowsy, have a reduced level of consciousness or feel faint or dizzy upon standing.
- Have heart problems or heart disease.

- Have low blood pressure.
- Have a chronic lung disease.
- Suffer from sleep apnoea (temporarily stopping breathing while you sleep).
- Have just drunk a large amount of alcohol, regularly drink large amounts of alcohol or have confusion and shaking due to stopping drinking alcohol.
- Suffer from convulsions, fits or seizures.
- Have a head injury, brain tumour or increased pressure in your head.
- Are about to have surgery, had recent gastrointestinal surgery or have had other surgery in the last 24 hours.
- Have chronic liver or kidney disease.
- Have problems with your oesophagus, such as difficulty swallowing, heartburn or reflux
- Have increased prostate size or difficulty passing urine.
- Have problems with your gall bladder or bile ducts.
- Have problems with or recent surgery of your bile duct.
- Have inflammation of the pancreas.
- Have adrenal glands which are not working properly.
- Have an underactive thyroid gland.
- Have a severe mental condition involving losing contact with reality or an inability to think clearly.
- Suffer from major depression, anxiety or a personality disorder.
- Have 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.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Low levels of opioids have been detected in human milk.

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

Addiction

You can become addicted to hydromorphone even if you use it exactly as prescribed. Hydromorphone 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 receiving hydromorphone. Using it may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop using hydromorphone suddenly, so it is important to use it exactly as directed by your doctor.

Tolerance

Tolerance to hydromorphone 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 using 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 hydromorphone and affect how it works.

Using hydromorphone with medicines that can make you feel drowsy may result in severe drowsiness, decreased awareness, breathing problems, coma and death. These medicines include:

- sleeping tablets and other sedatives (including benzodiazepines and barbiturates)
- gabapentinoids (e.g. gabapentin and pregabalin)
- cannabis
- antihistamines
- anxiolytics (for managing anxiety)
- general anaesthetics
- antiemetics (for treating nausea and vomiting)
- antidepressants (including tricyclic antidepressants),
- antipsychotics (including phenothiazines)
- other opioids
- alcohol.

Hydromorphone may enhance the action of neuromuscular blocking agents and affect your breathing.

Hydromorphone should not be used if you are taking non-selective monoamine oxidase inhibitors (MAOIs) or within 14 days of stopping such treatment.

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

4. How do I use HYDROMORPHONE JUNO/JUNO-HP/JUNO-XHP?

How much to use

- Your doctor will decide the appropriate dose for you.

When to use hydromorphone

- You will be given hydromorphone injections as directed by your doctor.

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

How to use hydromorphone

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

Hydromorphone injections can be given as a single injection or infusion into the vein. It can also be administered through a fine needle into the tissue under the skin or into the muscle.

Your doctor will decide the most appropriate way for you to be given hydromorphone. Using this medicine in a manner other than that prescribed by your doctor can be harmful to your health.

If you forget to use hydromorphone

If you miss your dose at the usual time, contact your doctor, nurse or pharmacist for advice.

You should not receive a double dose to make up for the dose that you missed, as this may increase the chance of getting unwanted side effects.

If you use too much hydromorphone

If you or someone else has received 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 hydromorphone 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 hydromorphone 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 HYDROMORPHONE JUNO/JUNO-HP/JUNO-XHP?

Things you should do

Call your doctor straight away if you:

- become pregnant
- feel your pain is getting worse.

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

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

Things you should not do

Do not stop using this medicine suddenly without your doctor's advice. If you stop taking this medicine suddenly, your pain may worsen and you may experience withdrawal symptoms.

Do not use hydromorphone to treat any other complaint unless your doctor tells you to.

Do not give this medicine to anyone else, even if they have the same condition as you.

Driving or using machines

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

Hydromorphone may cause drowsiness or impair mental and/or physical ability in some people.

Drinking alcohol

Tell your doctor if you drink alcohol.

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

Looking after your medicine

Store 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
- in the car or on windowsills.

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 your doctor tells you to stop having this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

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

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

Less serious side effects

Less serious side effects	What to do
<p>Gastrointestinal and urinary related:</p> <ul style="list-style-type: none">constipationnausea or vomitingdifficulty urinating <p>Neurological and behavior related:</p> <ul style="list-style-type: none">dizzinessdrowsinessheadache <p>Endocrine related:</p> <ul style="list-style-type: none">problems with your adrenal glands including nausea, vomiting, anorexia, fatigue, weakness, dizziness, or low blood pressureAndrogen deficiency with symptoms such as low libido, impotence, erectile dysfunction, no menstrual period or infertility <p>Skin related</p> <ul style="list-style-type: none">sweatingitchiness or rash	<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
<p>Breathing related</p> <ul style="list-style-type: none">difficulty breathing or shallow breathing <p>Neurological and behaviour related:</p> <ul style="list-style-type: none">light-headedness, fainting or dizziness especially when standing upchanges in mooddrowsiness or feeling extremely sedatedfeeling disorientated or having hallucinationsseizures (fits) <p>Heart related:</p> <ul style="list-style-type: none">slow, fast or irregular heartbeats	<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>

<p>Gastrointestinal and urinary related:</p> <ul style="list-style-type: none">severe stomach pain with nausea or vomitingdifficulty urinatinginflammation of the pancreas (sudden severe upper abdominal pain that may spread to the back) <p>Allergy related</p> <ul style="list-style-type: none">shortness of breath, swelling of the face, lips, tongue or other parts of the body	
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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 HYDROMORPHONE JUNO/JUNO-HP/JUNO-XHP contains

Active ingredient (main ingredient)	hydromorphone hydrochloride
Other ingredients (inactive ingredients)	sodium citrate citric acid monohydrate sodium chloride water for injections.
Allergen information	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 the ingredients contained in this product.

What HYDROMORPHONE JUNO/JUNO-HP/JUNO-XHP looks like

A clear, colourless to pale yellow solution in a clear glass ampoule.

Australian registration numbers:

- HYDROMORPHONE JUNO 2 mg in 1 mL injection solution AUST R 303503.
- HYDROMORPHONE JUNO-HP 10 mg in 1 mL injection solution AUST R 303502.
- HYDROMORPHONE JUNO-HP 50 mg in 5 mL injection solution AUST R 303504.
- HYDROMORPHONE JUNO-XHP 50 mg in 1 mL concentrated injection AUST R 303505.

Who distributes HYDROMORPHONE JUNO/JUNO-HP/JUNO-XHP

Juno Pharmaceuticals Pty Ltd
15-17 Chapel Street
Cremorne VIC 3121

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