

HYDROMORPHONE-HAMELN/HYDROMORPHONE-HAMELN-HP INJECTION

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-HAMELN/HYDROMORPHONE-HAMELN-HP ?

HYDROMORPHONE-HAMELN/HYDROMORPHONE-HAMELN-HP contains the active ingredient hydromorphone hydrochloride. HYDROMORPHONE-HAMELN/HYDROMORPHONE-HAMELN-HP 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-HAMELN/HYDROMORPHONE-HAMELN-HP?](#) in the full CMI.

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

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-HAMELN/HYDROMORPHONE-HAMELN-HP ?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with HYDROMORPHONE-HAMELN/HYDROMORPHONE-HAMELN-HP 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-HAMELN/HYDROMORPHONE-HAMELN-HP?

- Your doctor will tell you exactly how much to take.
- Follow the instructions given to you by your doctor or pharmacist exactly.
- HYDROMORPHONE-HAMELN/HYDROMORPHONE-HAMELN-HP Injection must only be administered by injection.

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

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

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using HYDROMORPHONE-HAMELN/HYDROMORPHONE-HAMELN-HP• 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
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly• Do not take more than your doctor tells you to
Driving or using machines	<ul style="list-style-type: none">• HYDROMORPHONE-HAMELN/HYDROMORPHONE-HAMELN-HP may cause drowsiness, if affected do not drive a vehicle or operate machinery.
Drinking alcohol	<ul style="list-style-type: none">• Avoid alcohol• Alcohol 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**

- Store below 30°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-HAMELN/HYDROMORPHONE-HAMELN-HP?](#) in the full CMI.

6. Are there any side effects?

HYDROMORPHONE-HAMELN/HYDROMORPHONE-HAMELN-HP 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.

WARNING:**Limitations of use**

HYDROMORPHONE-HAMELN/HYDROMORPHONE-HAMELN-HP 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-HAMELN/HYDROMORPHONE-HAMELN-HP 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

HYDROMORPHONE-HAMELN/HYDROMORPHONE-HAMELN-HP 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 HYDROMORPHONE-HAMELN/HYDROMORPHONE-HAMELN-HP 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 HYDROMORPHONE-HAMELN/HYDROMORPHONE-HAMELN-HP

Using HYDROMORPHONE-HAMELN/HYDROMORPHONE-HAMELN-HP 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 HYDROMORPHONE-HAMELN/HYDROMORPHONE-HAMELN-HP.

HYDROMORPHONE- HAMELN/HYDROMORPHONE-HAMELN-HP Injection

Active ingredient(s): *Hydromorphone Hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using HYDROMORPHONE-HAMELN/HYDROMORPHONE-HAMELN-HP. **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 HYDROMORPHONE-HAMELN/HYDROMORPHONE-HAMELN-HP.**

Where to find information in this leaflet:

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

1. Why am I using HYDROMORPHONE-HAMELN/HYDROMORPHONE-HAMELN-HP?

HYDROMORPHONE-HAMELN/HYDROMORPHONE-HAMELN-HP contains the active ingredient hydromorphone hydrochloride. Hydromorphone belongs to a group of medicines called opioid analgesics.

HYDROMORPHONE-HAMELN/HYDROMORPHONE-HAMELN-HP is used to provide the 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-HAMELN/HYDROMORPHONE-HAMELN-HP?**Warnings**

Do not use HYDROMORPHONE-HAMELN/HYDROMORPHONE-HAMELN-HP if:

- you are allergic to hydromorphone 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.

- you have acute breathing difficulties such as bronchitis or asthma
- 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:

- are severely drowsy, have a reduced level of consciousness or are feeling faint or dizzy upon standing
- have heart problems or heart disease
- have low blood pressure
- have 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 increased prostate size or difficulty passing urine
- have problems with your gall bladder
- 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 opioid analgesics have been detected in human milk.

HYDROMORPHONE-HAMELN/HYDROMORPHONE-HAMELN-HP given to the mother during labour can cause breathing problems and signs of withdrawal in the newborn.

Addiction

You can become addicted to HYDROMORPHONE-HAMELN/HYDROMORPHONE-HAMELN-HP even if you take it exactly as prescribed. HYDROMORPHONE-HAMELN/HYDROMORPHONE-HAMELN-HP 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 HYDROMORPHONE-HAMELN/HYDROMORPHONE-HAMELN-HP. Taking it may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop taking HYDROMORPHONE-HAMELN/HYDROMORPHONE-HAMELN-HP suddenly, so it is important to take it exactly as directed by your doctor.

Tolerance

Tolerance to HYDROMORPHONE-HAMELN/HYDROMORPHONE-HAMELN-HP 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 HYDROMORPHONE-HAMELN/HYDROMORPHONE-HAMELN-HP and affect how it works.

Using HYDROMORPHONE-HAMELN/ HYDROMORPHONE-HAMELN-HP 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
- cannabis
- antihistamines
- anxiolytics
- general anaesthetics
- antiemetics
- antidepressants (including tricyclic antidepressants),
- antipsychotics (including phenothiazines)
- other opioids
- alcohol

HYDROMORPHONE-HAMELN/ HYDROMORPHONE-HAMELN-HP may enhance the action of neuromuscular blocking agents and affect your breathing.

HYDROMORPHONE-HAMELN/ HYDROMORPHONE-HAMELN-HP 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 affect HYDROMORPHONE-HAMELN/HYDROMORPHONE-HAMELN-HP.

4. How do I use HYDROMORPHONE-HAMELN/HYDROMORPHONE-HAMELN-HP?

How much to take/use

- Your doctor will decide the appropriate dose for you

When to take HYDROMORPHONE-HAMELN/HYDROMORPHONE-HAMELN-HP

You should be given HYDROMORPHONE-HAMELN or HYDROMORPHONE-HAMELN-HP 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 take HYDROMORPHONE-HAMELN/HYDROMORPHONE-HAMELN-HP

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

HYDROMORPHONE-HAMELN and HYDROMORPHONE-HAMELN -HP 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 have HYDROMORPHONE-HAMELN/HYDROMORPHONE-HAMELN-HP. 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-HAMELN/HYDROMORPHONE-HAMELN-HP

If you forget to have a dose, contact your doctor or pharmacist for advice.

Do not take a double dose to make up for the dose you missed.

This may increase the chance of getting unwanted side effects including severe drowsiness, decreased awareness, breathing problems, coma and death.

If you use too much HYDROMORPHONE-HAMELN/ HYDROMORPHONE-HAMELN-HP

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 HYDROMORPHONE-HAMELN/ HYDROMORPHONE-HAMELN-HP that was prescribed for you. If someone takes an overdose, they may experience one or more of the following symptoms:

- slow, unusual or difficult breathing
- drowsiness, dizziness or unconsciousness
- slow or weak heartbeat
- nausea or vomiting
- convulsions or fits

If you think that you have used too much HYDROMORPHONE-HAMELN/ HYDROMORPHONE-HAMELN-HP, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

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

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

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 health professionals as appropriate] you visit that you are using HYDROMORPHONE-HAMELN/HYDROMORPHONE-HAMELN-HP.

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. If you stop taking this medicine suddenly, your pain may worsen and you may experience withdrawal symptoms.

Do not take HYDROMORPHONE-HAMELN/HYDROMORPHONE-HAMELN-HP Injection or oral liquid 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-HAMELN/HYDROMORPHONE-HAMELN-HP affects you.

HYDROMORPHONE-HAMELN/HYDROMORPHONE-HAMELN-HP 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 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

- Store below 30°C

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on 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 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">• constipation• nausea or vomiting• difficulty urinating Neurological and behaviour related: <ul style="list-style-type: none">• dizziness• drowsiness• headache Allergy related <ul style="list-style-type: none">• sweating	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Breathing related <ul style="list-style-type: none">• difficulty breathing or shallow breathing Neurological and behaviour related: <ul style="list-style-type: none">• light-headedness, fainting or dizziness especially when standing up• changes in mood• drowsiness or feeling extremely sedated• feeling disorientated and having nightmares Heart related: <ul style="list-style-type: none">• slow or noticeable heartbeats Gastrointestinal and urinary related: <ul style="list-style-type: none">• severe stomach pain with nausea or vomiting• difficulty urinating Allergy related <ul style="list-style-type: none">• shortness of breath, swelling of the face, lips, tongue or other parts of the body	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

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-HAMELN/HYDROMORPHONE-HAMELN-HP contains

Active ingredient (main ingredient)	Hydromorphone hydrochloride
Other ingredients (inactive ingredients)	sodium citrate dihydrate citric acid sodium chloride hydrochloric acid or sodium hydroxide water for injections

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

What HYDROMORPHONE-HAMELN/HYDROMORPHONE-HAMELN-HP looks like

HYDROMORPHONE-HAMELN/HYDROMORPHONE-HAMELN-HP Injections are clear, colourless to pale yellow solution packed in a clear glass ampoule

HYDROMORPHONE-HAMELN hydromorphone hydrochloride 2 mg/1 mL injection ampoule (Aust R 342170)

HYDROMORPHONE-HAMELN-HP hydromorphone hydrochloride 10 mg/1 mL injection ampoule (Aust R 342171)

Who distributes HYDROMORPHONE-HAMELN/HYDROMORPHONE-HAMELN-HP

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

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