

# MEDSURGE HYDROMORPHONE INJECTION/ HYDROMORPHONE HP INJECTION/ HYDROMORPHONE XHP CONCENTRATED INJECTION

*Hydromorphone hydrochloride*

## Consumer Medicine Information

### WARNING:

#### Limitations of use

**HYDROMORPHONE/HYDROMORPHONE HP/HYDROMORPHONE XHP injections 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/HYDROMORPHONE HP/HYDROMORPHONE XHP injections 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/HYDROMORPHONE HP/HYDROMORPHONE XHP injections 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/HYDROMORPHONE HP/HYDROMORPHONE XHP injections 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/HYDROMORPHONE HP/HYDROMORPHONE XHP**

**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/HYDROMORPHONE HP/HYDROMORPHONE XHP injections.**

### What is in this leaflet

This leaflet answers some common questions about Medsurge Hydromorphone, Medsurge Hydromorphone HP (HP = High Potency) and Medsurge Hydromorphone XHP (XHP = Extra High Potency) injections.

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

All medicines have benefits and risks. Your doctor has weighed the benefits of you using this medicine against the risks it may have for you.

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

**Keep this leaflet in a safe place.**

You may need to read it again.

### What Hydromorphone injections are used for

Medsurge Hydromorphone, Hydromorphone HP and Hydromorphone XHP injections contain HYDROMORPHONE hydrochloride. Hydromorphone belongs to a group of medicines called opioid analgesics.

Medsurge Hydromorphone/Hydromorphone HP/Hydromorphone XHP injections 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. They can be given as a single injection, or as an infusion into a vein, or as an injection into the tissue under the skin, or as an injection into the muscle.

Opioid analgesics have been used to treat pain for many years. 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.**

As with all strong painkillers, your body may become used to you having hydromorphone. Being given it may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop having hydromorphone suddenly, so it is important that you are given Hydromorphone hydrochloride injections exactly as directed by your doctor.

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

### Before you use Hydromorphone injections

*When you must not have it*

**You should not have Hydromorphone hydrochloride injections if you:**

- suffer from shallow or difficult breathing or have any acute breathing problems such as bronchitis or asthma
- have severe abdominal pain with bloating, cramps or vomiting
- have a condition where your small bowel does not work properly
- take medicine for depression called a 'monoamine oxidase inhibitor' or have taken any in the last two weeks
- have been prescribed Medsurge Hydromorphone HP injection or Medsurge Hydromorphone XHP concentrated injection and you have not used any opioid medicine before.

**You should not have Hydromorphone hydrochloride injections if you are allergic to HYDROMORPHONE hydrochloride, opioid analgesics, or any of the ingredients listed at the end of this leaflet.**

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

If you have it after the expiry date has passed, it may not work very well or may no longer be sterile.

**Do not use this medicine if the packaging is damaged or shows signs of tampering or if the solution in the ampoule shows any visible signs of deterioration.**

**Do not have this medicine during labour for the delivery of premature infants.**

**Hydromorphone given to the mother can cause breathing problems in the newborn, especially premature babies.**

**Do not have this medicine if you are pregnant or intend to become pregnant whilst having this medicine.**

Like most medicines of this kind, Hydromorphone hydrochloride injections should not be given during pregnancy. Your doctor will discuss the risks of having it if you are pregnant.

**Do not give this medicine to a child, and especially not to a premature newborn.**

Safety and efficacy in children have not been established.

### Before you start to take it

**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:**

- are severely drowsy, have a reduced level of consciousness or are feeling faint or dizzy upon standing
- heart problems or heart disease
- low blood pressure
- 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
- convulsions, fits or seizures
- head injury, brain tumour or increased pressure in your head
- are about to have surgery or have had surgery in the last 24 hours
- recent gastrointestinal surgery
- chronic liver or kidney disease
- increased prostate size or difficulty passing urine
- problems with or recent surgery of your bile duct
- problems with your gall bladder
- inflammation of the pancreas
- adrenal glands not working properly
- underactive thyroid gland
- severe mental condition involving losing contact with reality or an inability to think clearly
- an addiction or history of abuse of alcohol, opioids or other drugs.

**Check with your doctor if you are pregnant or intend to become pregnant.**

**Tell your doctor if you are breastfeeding or intend to breastfeed.**

Low levels of opioid analgesics have been detected in human milk.

### Addiction

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

#### **Tolerance**

Tolerance to hydromorphone hydrochloride 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.

**Hydromorphone/Hydromorphone HP/Hydromorphone XHP injections given to the mother during labour can cause breathing problems and signs of withdrawal in the newborn.**

**If you have not told your doctor about any of the above, tell them before you have Hydromorphone/Hydromorphone HP/Hydromorphone XHP injections.**

#### **Taking other medicines**

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

Some medicines and Hydromorphone hydrochloride injections may interfere with each other. Using hydromorphone hydrochloride injections with medicines that can make you feel drowsy may result in severe drowsiness, decreased awareness, breathing problems, coma and death. These 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 hydrochloride injections may enhance the action of neuromuscular blocking agents and affect your breathing.

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

These medicines and alcohol may be affected by Hydromorphone hydrochloride injections, may affect how well Hydromorphone hydrochloride injections work or may increase side effects. You may need to use different amounts of your medicines or take different medicines.

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

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### **Taking Hydromorphone injections**

#### *How much is given*

**Your doctor will decide the appropriate dose for you.**

#### *How it is given*

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

**Hydromorphone hydrochloride 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. Using this medicine in a manner other than that prescribed by your doctor can be harmful to your health.

#### *When it is given*

**You should be given Hydromorphone hydrochloride injections as directed by your doctor.**

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

#### *How long it is given for*

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

If you stop having this medicine suddenly, your pain may worsen and you may experience withdrawal symptoms such as:

- body aches
- loss of appetite, nausea (feeling sick), stomach cramps or diarrhoea
- fast heart rate
- sneezing or runny nose
- chills, tremors, shivering or fever
- trouble sleeping, nervousness or restlessness
- increased sweating and yawning
- weakness.

#### *If you forget to have it*

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

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

Having extra medicine will increase the chance of an unwanted side effects.

#### *If you have received too much (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 hydromorphone hydrochloride that was prescribed for you. If someone has 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 hydrochloride, 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.

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### **While you are being given Hydromorphone injections**

#### *Things you must do*

**You should be given Hydromorphone hydrochloride injections exactly as your doctor has prescribed.**

**Before you start on a new medicine, remind your doctor and pharmacist you are having Hydromorphone hydrochloride injections.**

**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 having 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. Also discuss any problems or difficulties you have while you are having this medicine with your doctor.

Tolerance to hydromorphone 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 use Hydromorphone hydrochloride injections 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.**

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

Over time your body may become used to hydromorphone so if you stop having it suddenly, your 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 you have each day, if possible, before stopping the medicine completely.

**Do not drink alcohol while you are having this medicine.**

Drinking alcohol while using this medicine 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.

*Things to be careful of*

**Tell your doctor if you find that you cannot concentrate or that you feel more sleepy than normal when you start having this medicine or when the dose is increased.**

**This feeling should wear off after a few days.**

**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.**

**Do not drive or operate machinery until you know how Hydromorphone hydrochloride injections affect you.**

As with other opioid analgesics, Hydromorphone hydrochloride injections may cause drowsiness, dizziness, hallucinations, disorientation, blurred vision or other vision problems or may affect alertness. Discuss these aspects and any impact on your driving or operating machinery with your doctor.

**Be careful if you are elderly, unwell or taking other medicines.**

Some people may experience side effects such as unsteadiness, dizziness, drowsiness or confusion which may increase the risk of a fall.

**Tell your doctor if you suffer from nausea or vomiting when having Hydromorphone hydrochloride injections.**

**Your doctor may be able to give you some medicine to help.**

**Tell your doctor if having Hydromorphone hydrochloride injections causes constipation.**

**Your doctor can advise you about your diet, the proper use of laxatives and other ways to help manage constipation.**

**There is potential for abuse of hydromorphone and the development of addiction to hydromorphone. It is important that you discuss this issue with your doctor.**

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#### Side effects

All medicines may have some unwanted side effects. Sometimes they are serious but most

of the time they are not. 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 Hydromorphone hydrochloride injection.**

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

**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 problems such as, feeling nauseous (feeling sick), loss of appetite, constipation or diarrhoea
- dry mouth or changes in taste
- feeling agitated, nervous or anxious
- have trouble sleeping
- trouble with your balance
- problems with your eyesight
- skin rash, itching or sweating
- uncoordinated muscle movements and stiffness, tremor, tingling and numbness
- feeling faint
- swelling, including but not only, of the legs or ankles
- redness and soreness at site of injection
- chills
- erectile dysfunction.

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

- stomach discomfort or cramps, vomiting, indigestion or abdominal pain
- changes in mood
- light-headedness, fainting or dizziness especially when standing up
- drowsiness or feeling extremely sedated
- feeling disorientated and having nightmares
- slow or noticeable heartbeats
- headache, confusion or hallucinations
- unusual weakness or loss of strength
- difficulty passing urine, pain or feeling the need to urinate urgently.

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 your nearest hospital:**

- your breathing slows or weakens
- you have an allergic reaction: shortness of breath, wheezing, shallow or difficult breathing; swelling of the tongue, throat, face, lips or other parts of the body; rash, itching or hives on the skin
- seizures, fits or convulsions
- fast or irregular heartbeats.

**The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.**

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

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#### After being given Hydromorphone injections

##### Storage

**Hydromorphone hydrochloride injections should be given immediately after opening the ampoule. Once opened, any unused portion should be discarded.**

**If you are having Hydromorphone hydrochloride injections in hospital, the ampoules will be stored in the pharmacy or on the ward.**

**If you have some of this medicine at home, keep the 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 window sill.**

**Do not leave it in the car.**

Heat 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 expiry date has passed, ask your pharmacist how to dispose of medicines no longer required.**

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#### Product description

##### What it looks like

Medsurge Hydromorphone injection, Medsurge Hydromorphone HP injection and Medsurge Hydromorphone XHP concentrated injection comes in amber glass ampoules containing a clear, colourless to yellowish solution.

There are different strengths and presentations available:

Strength	Pack size
2 mg/1 mL	5 x 1 mL, 10 x 1 mL
10 mg/1 mL	5 x 1 mL, 10 x 1 mL
100 mg/10 mL	5 x 10 mL, 10 x 10 mL
20 mg/1 mL	5 x 1 mL, 10 x 1 mL
50 mg/1 mL	5 x 1 mL, 10 x 1 mL

Not all presentations and/or pack sizes are marketed.

##### Ingredients

As well as HYDROMORPHONE hydrochloride, the active ingredient, the ampoules also contain sodium citrate dihydrate, citric acid, sodium chloride, hydrochloric acid or sodium hydroxide (to adjust pH) and water for injections.

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

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#### Sponsor

##### Australian Sponsor

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**Marketed and distributed by**



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*Registration Numbers*

MEDSURGE HYDROMORPHONE 2 mg/1 mL AUST R 309688

MEDSURGE HYDROMORPHONE HP 10 mg/1 mL AUST R 309689

MEDSURGE HYDROMORPHONE HP 20 mg/1 mL AUST R 309683

MEDSURGE HYDROMORPHONE HP 100 mg/10 mL AUST R 309682

MEDSURGE HYDROMORPHONE XHP 50 mg/1 mL AUST R 309686

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