Package leaflet: Information for the user

Hydromorphone Hydrochloride 20mg/ml Solution for Injection/Concentrate for Solution for Infusion

Hydromorphone Hydrochloride 50mg/ml Solution for Injection/Concentrate for Solution for Infusion

Hydromorphone Hydrochloride (referred to as Hydromorphone Injection in this leaflet)

Read all of this leaflet carefully before you are given Hydromorphone Injection because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Hydromorphone Injection is and what it is used for

Hydromorphone hydrochloride, the active ingredient in Hydromorphone Injection, is a powerful pain killer.
Hydromorphone Injection is used to treat long lasting severe pain.

2. What you need to know before you are given Hydromorphone Injection

You should not be given Hydromorphone Injection if:

- you are allergic to hydromorphone hydrochloride or to any of the other ingredients in this medicine, (listed in section 6)
- have severe pain in your abdomen;
- have a condition where the small bowel does not work properly (paralytic ileus);
- you suffer from any breathing difficulties or problems with your lungs such as severe chronic obstructive pulmonary disease, cor pulmonale (a heart condition caused by lung disease),
- you are taking or have recently (in the last two weeks) taken any medicines used to treat depression known as Monoamine Oxidase Inhibitors (MAOI's) (see 'Taking other medicines').

Warnings and precautions

Talk to your doctor, pharmacist or nurse before receiving Hydromorphone Injection if you:

- you suffer from severe liver or kidney problems (including ureteric colic);
- you suffer from problems with your prostate (such as difficulties in passing urine);
- you suffer from an underactive thyroid (hypothyroidism);
- you suffer from low blood pressure associated with low circulating blood volume (hypotension

with hypovolaemia);

- you suffer from problems related to your adrenal gland (the organ responsible for stress levels), including Addison's disease (an illness caused by a lack of the hormone cortisol, which controls stress levels)
- your doctor has told you that you are suffering from a disorder known as toxic psychosis which affects the way you think
- you suffer from problems with your gallbladder
- you are suffering from a condition known as delirium tremens ('DT's) caused by withdrawal from alcohol
- you suffer from seizures, fits or convulsions
- you have a head injury (due to the risk of increased brain pressure);
- you have previously suffered from withdrawal symptoms such as agitation, anxiety, nervousness, difficulty in sleeping, being unusually overactive, shaking and gastrointestinal problems upon stopping taking alcohol or drugs;
- you are feeling light-headed or faint;
- you have inflammation of the pancreas (pancreatitis);
- you have any bowel problems (such as obstructive or inflammatory bowel disease);
- you have a chronic obstructive airway disease (such as COPD) or reduced pulmonary function;
- you suffer from a debilitated general condition or are elderly;
- you or anyone in your family have ever been dependent on alcohol, prescription medicines or illegal drugs ("addiction");
- you are a smoker;
- you have ever had problems with your mood (depression, anxiety or a personality disorder) or have been treated by a psychiatrist for other mental illnesses;

Tolerance and dependence

This medicine contains hydromorphone which is an opioid medicine. After prolonged use of Hydromorphone Injection, it is possible to develop tolerance and dependence on the medicine. If you feel that Hydromorphone Injection is no longer providing adequate pain relief you should talk to your doctor.

The major risk of opioid excess is difficulty in breathing (respiratory depression).

Patients may develop tolerance with long-term use of this medicine. This means you may require higher doses to achieve the desired pain control.

Long-term use of this medicine may lead to physical dependence and abuse which may result in life-threatening overdose. If you have concern that you may become dependent on this medicine, it is important that you consult your doctor. If treatment is stopped abruptly, withdrawal symptoms such as agitation, anxiety, nervousness, difficulty in sleeping, involuntary muscle contractions, shaking, and gastrointestinal problems may occur. If you no longer require therapy with hydromorphone, your doctor will taper the daily dose gradually to prevent these symptoms.

The active substance hydromorphone hydrochloride has an abuse profile similar to other strong opioids. There is potential for development of psychological dependence. Therefore, this medicine should be used with particular care in patients with a history of alcohol and drug abuse.

An increase in sensitivity to pain (hyperalgesia) that will not respond to a further dose increase of this medicine may occur in particular in high doses. Your doctor will decide whether a dose reduction or change in analgesic (opioid) is required in such a situation.

Please tell your doctor if you experience small bowel problems (paralytic ileus) during treatment with this medicine. He or she will take appropriate measures.

If you are going to have an operation, please tell the doctor at the hospital that you are using this medicine as they may need to adjust the amount of injection you are given.

The use of this medicine may produce positive results in doping controls.

Children and adolescents

Hydromorphone Injection is not recommended for children under 12 years of age.

Other medicines and Hydromorphone Injection

Tell your doctor if you:

- are taking medicines to treat anxiety (for example tranquillisers);
- have been given an anaesthetic (for example a barbiturate);
- are taking medicines to help you sleep (benzodiazepines, hypnotics or sedatives);
- are taking medicines to treat psychiatric or mental disorders (neuroleptics or psychotropics);
- are taking medicines to treat depression (antidepressants);
- are taking medicines used to stop you feeling sick or being sick (antiemetics);
- are taking medicines used to prevent or relieve the symptoms of an allergy (antihistamines);
- are taking medicines to treat Parkinson's disease;
- are taking other strong analgesics or 'painkillers' or have recently taken another painkiller from the opioid class.

The concomitant use of opioids and drugs to treat epilepsy, nerve pain or anxiety (gabapentin and pregabalin) increases the risk of opioid overdose, respiratory depression and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.

However, if your doctor does prescribe Hydromorphone injection together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all sedative medicines you are taking and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

Sleep related sleeping disorders

Hydromorphone hydrochloride can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep related hypoxemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day. If you or another person observe these symptoms, contact your doctor. A dose reduction may be considered by your doctor.

Hydromorphone injection with food, drink and alcohol

Drinking alcohol during your treatment with this medicine may make you drowsy. If you are affected you should avoid drinking alcohol.

Pregnancy, breast-feeding and fertility:

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine

Pregnancy

You should not use this medicine during pregnancy and labour unless you have been specifically told by your doctor. If you use this medicine during labour, uterine contractility may be impaired. In addition, slow and shallow breathing (respiratory depression) may occur in the newborn infant.

Newborn babies may suffer withdrawal effects (such as highpitched cry, jitteriness, fits, poor feeding and diarrhoea) if their mothers have taken hydromorphone for a long-time during pregnancy.

Breast-feeding

You should not be given this medicine if you are breast-feeding as Hydromorphone Injection can pass into breast milk.

Driving and using machines:

This medicine can affect your ability to drive and operate machinery. This is particularly likely at the initiation of treatment with hydromorphone, after dose increase or product rotation and if hydromorphone is combined with alcohol or other CNS depressant substances. Do not drive or operate machinery if you feel drowsy or cannot think clearly. You should consult your doctor before driving or using machinery.

Hydromorphone Injection contains sodium

This medicine contains less than 1 mmol sodium (23mg) per dose, that is to say essentially 'sodium-free'

3. How Hydromorphone Injection is given

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

This medicine is an injection and will be given to you by your doctor or nurse either, under your skin or by slow injection into a vein (infusion). Your doctor will determine the dose you require.

Adults and adolescents (older than 12 years)

As an injection under the skin (subcutaneous use): 1 to 2 mg. This can be repeated every 3 - 4 hours.

As an injection into a vein (Intravenous use): 1 to 1.5mg given slowly over 2 to 3 minutes. This can be repeated every 3 to 4 hours.

As an infusion into a vein (Intravenous use) or under the skin (subcutaneous use): 0.15 to 0.45mg/h (or 0.004mg/kg body weight per hour).

If given by patient controlled analgesia (PCA): 0.2mg with a stop interval of 5 to 10 minutes.

Use in elderly patients (over 75 years of age)

A lower dosage might be enough for adequate pain relief in elderly patients.

Use in patients with liver and kidney problems

If you suffer from liver or kidney problems, you may require less of this medicine in order to relieve your pain.

Children under 12 years

This medicine is not recommended for children under 12 years.

Duration of treatment

This medicine should only be used as long as necessary. Your doctor will decide when and how the treatment will be stopped. If you get long term treatment, your doctor should verify regularly whether you still need this medicine. Do not stop the treatment without talking to your doctor (see "If you stop using Hydromorphone injection").

If you think you have been given too much Hydromorphone Injection

This medicine is given to you by your doctor or nurse so it is unlikely you will receive too much. You doctor has information on how to recognize and treat an overdose. If you are concerned about your treatment call your doctor, hospital or an ambulance straight away as you may need emergency treatment in hospital.
In severe cases an overdose may lead to unconsciousness, pneumonia caused by inhaling vomit or foreign matter (symptoms may include breathlessness, cough and fever) or even death. The following symptoms may occur after an overdose:
pin point pupils;
slowing of heartbeat;
respiratory problems;
low blood pressure;
unconsciousness leading to coma.
breathlessness, cough and fever.

If you stop using Hydromorphone injection

You should not suddenly stop using this medicine unless your doctor tells you to. If you want to stop using this medicine discuss this with your doctor first. If you do stop using this medicine suddenly after extended treatment, you may experience withdrawal symptoms such as agitation, anxiety, nervousness, difficulty in sleeping, involuntary muscle contractions, shaking, and gastro-intestinal problems. Your doctor will tell you how to stop your treatment, usually by reducing the dose gradually so you do not experience unpleasant effects.
If you have any further questions on the use of this product, ask your doctor or nurse.

4. Possible side effects

Like all medicines Hydromorphone Injection can cause side effects although not everybody gets them.

This medicine can cause allergic reactions (hypersensitivity reactions). The incidence of serious allergic reactions (anaphylactic reactions) is not known. **Tell your doctor immediately** if you get any sudden wheeziness, difficulties in breathing, swelling of the eyelids, face, lips, mouth or throat, or any rash or itching especially those covering your whole body. Difficulty in breathing (respiratory depression) is the chief hazard of an opioid overdose.

Most people will have constipation when using this medicine. Increasing the amount of fibre (fruit, vegetables, wholemeal bread, pasta, brown rice) and fluids you eat and drink may help reduce the problem, but if necessary your doctor may prescribe a laxative.

You may feel sick or vomit (be sick) when you use this medicine, this should normally wear off after a few days however your doctor can prescribe an anti-vomiting medicine if it continues to be a problem.

Very common side effects (may affect more than 1 in 10 people)

- dizziness
- feel more sleepy than normal
- constipation
- feel sick

Common side effects (may affect up to 1 in 10 people) confusion

- anxiety
- sleeplessness
- headache
- dry mouth
- vomiting (being sick)
- itchy skin

- sweating
- urgency in passing urine
- a feeling of unusual weakness
- loss of appetite
- abdominal pain or discomfort
- skin reactions at the injection site

Uncommon side effects (may affect up to 1 in 100 people)

- feeling of extreme happiness
- hallucinations
- shaking
- muscle spasms
- tingling in the hands or feet
- blurred vision
- low blood pressure
- indigestion
- rash
- decreased sexual drive
- impotence
- withdrawal symptoms such as agitation, anxiety, nervousness, difficulty in sleeping, being unusually overactive, shaking and gastrointestinal problems
- tiredness
- generally feeling unwell
- swelling of hands, ankles or feet
- agitation
- depression
- nightmares
- shortness of breath
- diarrhoea
- changes in taste
- difficulty in passing urine
- a worsening in liver function tests (seen in a blood test)

Rare side effects (may affect up to 1 in 1,000 people)

- sedation
- lack of energy
- slow, fast or irregular heartbeat
- difficulty in breathing or wheezing
- a worsening in pancreas function tests (seen in a blood test)

Very rare side effects (may affect up to 1 in 10,000 people)

- irritation and hardening of the skin at the injection site (particularly after repeated subcutaneous administration)

Side effects with unknown frequency (frequency cannot be estimated from the available data)

- drug dependence
- drug tolerance
- unpleasant or uncomfortable mood
- reduction in size of the pupils in the eye
- an increase in sensitivity to pain (hyperalgesia; see “Warnings and precautions” in section 2)
- seizures
- fits or convulsions
- uncontrolled muscle movements
- facial flushing (redness of the face)
- a condition where the small bowel (part of your gut) does not work properly (paralytic ileus)
- itching rash (hives)
- withdrawal symptoms in babies born to mothers who have used hydromorphone (see “Pregnancy and breastfeeding” in section 2)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system:

Ireland

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2 Tel: +353 1 6764971
Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Hydromorphone Injection

Keep this medicine out of the sight and reach of children. This product should not be used after the expiry date which is printed on the carton and label after EXP. The expiry date refers to the last day of that month. Your doctor or nurse will check to make sure the product has not passed the expiry date before giving it to you.
Do not store above 25°C. Keep container in the outer carton in order to protect from light. This product should be used immediately after opening. This medicine will only be used for your treatment. Your doctor will not use this medicine if it has deteriorated. Your doctor will dispose of any left over medicine.

6. Contents of the pack and other information

What Hydromorphone Injection contains

The active ingredient is hydromorphone hydrochloride 20mg/ml or 50mg/ml.
Each 1ml 20mg/ml ampoule contains 20mg hydromorphone hydrochloride.
Each 1ml 50mg/ml ampoule contains 50mg hydromorphone hydrochloride.
The other ingredients are sodium citrate, citric acid monohydrate and water for injections.

What Hydromorphone Injection looks like and contents of the pack

Hydromorphone Injection is a clear, colourless solution for injection/concentrate for solution for infusion supplied in 1ml clear glass ampoules. The ampoules are packed in cardboard cartons and are available in packs of 10.

Marketing Authorisation Holder

Ethypharm
194, Bureaux de la Colline, Bâtiment D 92213, Saint-Cloud Cedex
France

Manufacturer:

Martindale Pharmaceuticals Ltd., Bampton Road, Harold Hill
Romford, Essex, RM3 8UG. UK

Fannin Limited
Fannin House,
South County Business Park,
Dublin 18,
D18 Y0C9,
Ireland

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