

Side Effects

Central Nervous System: Sedation, drowsiness, dry mouth, sweating, headache, facial flushing, hypothermia, hallucinations, lethargy, impairment of mental and physical performance, anxiety, fear, dysphoria, dizziness, psychological dependence, mood changes.

Gastrointestinal System: Nausea and vomiting occur infrequently; they are more frequent in ambulatory than in recumbent patients. Prolonged administration of Hydromorphone may produce constipation. Any opiate agonist-induced increase in intraluminal pressure may endanger surgical anastomosis.

Cardiovascular System: Circulatory depression, peripheral circulatory collapse and cardiac arrest have occurred after rapid intravenous injection. Orthostatic hypotension and fainting may occur if a patient stands up suddenly after receiving an injection of Hydromorphone. Bradycardia, tachycardia and palpitations may also occur.

Genitourinary System: Urethral spasm of vesical sphincters and urinary retention have been reported.

Respiratory Depression: Hydromorphone produces a dose-related respiratory depression by acting directly on brain stem respiratory centres. Hydromorphone also affects centres that control respiratory rhythm, and may produce irregular and periodic breathing.

Other side effects include; miosis, decreased libido, rashes, urticaria and pruritus. Pain at injection site and local tissue irritation following subcutaneous administration when repeated in the same area.

Drug abuse and Dependence: Hydromorphone is a narcotic. Psychological dependence, physical dependence, and tolerance may develop upon repeated administration. However, dependence is unlikely to develop when Hydromorphone is used for a short time for the treatment of pain. The rate of development of tolerance varies among patients.

Symptoms: Serious over-dosage is characterised by respiratory depression, extreme somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, and sometimes bradycardia and hypotension. Particularly by the intravenous route, apnoea, circulatory collapse, cardiac arrest, and death may occur.

Treatment: Attention should be given to the re-establishment of a patent airway and institution of assisted or controlled ventilation. The narcotic antagonist naloxone hydrochloride is a specific antidote against respiratory depression. Since the duration of action of Hydromorphone may exceed that of the naloxone, the patient should be kept under continued surveillance; repeated doses of naloxone may be required to maintain adequate respiration. Naloxone should not be administered in the absence of any clinically significant respiratory or cardiovascular depression. Rather oxygen, intravenous fluids, vasopressors, and other supportive measures should be employed

Pharmacodynamics

Hydromorphone is an opioid analgesic similar to morphine, with a longer duration of action. It is a strong agonist with actions predominantly at the μ receptor. These actions result in analgesia, respiratory depression, suppression of cough, nausea, vomiting and constipation. An effect on the nucleus of the oculomotor nerve, and perhaps on opioid receptors in the pupillary muscles, cause pupillary constriction. It causes a dependence syndrome of the morphine type. The greater lipid solubility and affinity for the μ receptor compared to morphine result in a greater analgesic effect with reduced nausea, vomiting and constipation compared to morphine.

Pharmacokinetics

Hydromorphone is rapidly but incompletely absorbed from the gastrointestinal tract following oral administration, oral bioavailability being about 50%. Following oral or intravenous administration, the plasma half life is about 2.5 hours. Hydromorphone is widely distributed in tissues and crosses the placenta. Hydromorphone is metabolised in the liver and excreted in the urine as conjugated hydromorphone, dihydromorphone and dihydroisomorphine.

Incompatibilities

Incompatible with minocycline and tetracycline solutions resulting in a colour change to light green, whilst cloudiness and precipitation result when hydromorphone is mixed with sodium thiopental. Mixtures with dexamethasone sodium phosphate, sodium bicarbonate and thiopental sodium exhibit a concentration dependent incompatibility and instability.

Container & contents

Clear colourless Type 1 glass ampoules packed in cardboard cartons.
Pack size: 10 x 1ml ampoules

Instructions for use/handling

Hydromorphone Injection must be diluted prior to administration by intravenous infusion. The following infusion fluids may be used:- 5% Dextrose in Water, 0.9% Sodium Chloride, Ringers Solution and Water for Injections.
For single use only.
Discard any unused contents.

Authorisation Holder

Martindale Pharmaceuticals Ltd
Bampton Road Romford RM3 8UG UK

Shelf Life:

Unopened: 3 years.
The product should be used immediately after opening.
Do not use if the product has deteriorated.
Do not store above 25°C. Keep container in the outer carton in order to protect from light.

Authorisation numbers

PA 361/18/1-2

Leaflet last revised: January 2017

Martindale
Pharmaceuticals

M

Bampton Road, Harold Hill, Romford, RM3 8UG, United Kingdom

Having Hydromorphone Injection with food and drink
You are advised not to drink alcohol during your treatment with Hydromorphone Injection.

3. How Hydromorphone Injection is given

This medicine is an injection and will be given to you by your doctor or nurse either into a muscle, 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)

Intramuscular administration: Initially, 1 to 2mg every 3 to 6 hours.

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.

Elderly

If you are elderly your doctor will reduce the initial dose.

Children under 12 years

This medicine is not recommended for children under 12 years.

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, please talk to your doctor.

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.

Tolerance, addiction and withdrawal

Repeated use of hydromorphone can result in tolerance and addiction. Prolonged use of this medicine can result in mental and physical dependence on hydromorphone which may result in withdrawal symptoms if your treatment is stopped too quickly. The withdrawal symptoms of Hydromorphone Injection include sweating, anxiety, difficulty sleeping, loss of appetite, pain, stomach cramps and diarrhoea. If you are worried about this possible side effect please talk to your doctor.

If you have been given Hydromorphone Injection during your pregnancy your baby may experience withdrawal symptoms shortly after birth. These symptoms include restlessness, jerking or shaking, sweating, fever, unusually fast breathing, poor feeding and projectile vomiting. If you are concerned about the possible side effects this medicine may have on your unborn child please talk to your doctor before being given this medicine.

Serious side effects:

- If any of the following symptoms occur tell your doctor immediately.
- sudden wheeziness and tightness of the chest
 - swelling of the eyelids, face or lips
 - skin lumps or hives
 - skin rash (red spots), itchiness, fever
 - collapse.

Other possible side effects include:

- feeling drowsy or sedated
- dry mouth
- sweating or facial flushing
- headache
- unusually low body temperature (hypothermia)
- seeing or hearing things that aren't real (hallucinations)
- lacking energy
- difficulty performing normal mental and physical tasks
- feeling anxious or scared

- feeling sad, worried or restless
- dizziness
- changes in mood
- feeling or being sick
- constipation
- slowed blood circulation or failure of the blood to circulate around your body which in severe cases could lead to gangrene or organ failure
- heart attack
- fainting or feeling faint on standing up from a seated position
- an unusually fast or slow heartbeat, or an awareness of your heart beating (palpitations)
- spasms in the lower abdomen
- difficulty passing urine
- slowed or irregular breathing
- pin-point pupils
- decreased libido
- a red or itchy rash
- pain at the site of injection.

If used during labour, Hydromorphone Injection can cause breathing difficulties in your newborn infant.

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. Storing Hydromorphone Injection

Keep all medicines out of the reach and sight 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. Further 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 and Manufacturer:

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

Marketing Authorisation Numbers:

PA 361/18/01 PA 361/18/02

Leaflet last revised: January 2017

Martindale
Pharmaceuticals

M

Bampton Road, Harold Hill, Romford, RM3 8UG, United Kingdom

D03659000000