

PACKAGE LEAFLET: INFORMATION FOR THE USER

Hyoscine 400 micrograms/ml Solution for Injection

Hyoscine Hydrobromide

(Referred to as Hyoscine Injection in this leaflet)

Read all of this leaflet carefully before you are given Hyoscine Injection

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

What is in this leaflet:

1. What Hyoscine Injection is and what it is used for
2. What you need to know before Hyoscine Injection is given
3. How Hyoscine Injection is given
4. Possible side effects
5. How to store Hyoscine Injection
6. Contents of the pack and other information

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

Hyoscine Injection is used to treat nausea (feeling sick), vomiting (being sick), vertigo, loss of balance and motion sickness. Hyoscine Injection is also used to prevent you from producing too much saliva if you have been given a general anaesthetic.

2. What you need to know before Hyoscine Injection is given

You should not be given Hyoscine Injection if you:

- are allergic to hyoscine hydrobromide or any of the other ingredients of this medicine listed in section 6.
- suffer from myasthenia gravis (extreme muscle weakness)
- suffer from megacolon (dilated large bowel)
- suffer from blockage of stomach (pyloric stenosis) or bowel
- suffer from an inactive or paralysed bowel (paralytic ileus)
- suffer from a racing heart
- are a man who has an enlarged prostate with urinary retention.
- suffer from an eye problem called angle-closure glaucoma
- are an elderly patient

Warnings and precautions

Tell your doctor or nurse before being given Hyoscine Injection if you:

- suffer from epilepsy, as there is an increased seizure frequency in epileptic patients
- have Down's Syndrome
- suffer from liver or kidney problems
- suffer from diarrhoea
- suffer from heart burn
- have a fever
- suffer from heart problems (i.e. heart attack, high blood pressure, heart failure or are undergoing cardiac surgery)
- suffer from overactive thyroid
- suffer from inflammation of the bowel (colitis)

Children:

Use with caution.

Children are more susceptible to side effects.

Please contact your doctor or nurse immediately if you experience severe persistent or worsening stomach pain;

together with, nausea, vomiting, changes in bowel movements, stomach tenderness, fainting or blood in your stool. If any of the above statements applies to you, please speak to your doctor or nurse before being given Hyoscine Injection. After receiving Hyoscine Injection, you may be kept under observation. This is a normal procedure.

If after receiving an injection of hyoscine you develop a painful, red eye with loss of vision please contact your doctor or nurse immediately.

Other medicines and Hyoscine Injection:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular:

- medicines used to treat an irregular heart beat e.g. disopyramide and quinidine.
- medicines use to treat respiratory conditions such as COPD (Chronic Obstructive Pulmonary Disease) and asthma e.g. tiotropium and ipratropium.
- medicines used to treat depression such as tricyclic and tetracyclic antidepressants.
- medicines used to treat hay fever and other allergies e.g. antihistamines.
- medicines used to relieve the symptoms of nausea and vomiting e.g. metoclopramide and domperidone.
- medicines used to control nausea (feeling sick) and vomiting (being sick) and to treat mental illness e.g. phenothiazines, butyrophenones and clozapine.
- medicines used for Parkinson's disease and influenza e.g. amantadine.

Hyoscine Injection may also reduce the effects of the following medicines:

- levodopa – Used to treat Parkinson's disease
- Nitrate (GTN) tablets – Used under the tongue for angina
- Parasympathomimetics – Used to treat conditions such as glaucoma, depression, asthma, heart conditions and retention of urine.

Hyoscine Injection and alcohol

You are advised not to drink alcohol whilst being treated with Hyoscine Injection, as it may cause drowsiness.

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

Use of Hyoscine Injection during pregnancy may cause breathing problems in the new-born infant. Use during pregnancy and breast feeding is not recommended.

Driving and using machines

Hyoscine Injection may cause drowsiness, dizziness or blurred vision. If affected, do not drive or operate any tools or machinery after you have been given Hyoscine Injection.

Hyoscine contains Sodium

This medicinal product contains 3.54mg/ml of sodium per dose. To be taken into consideration by patients on a controlled sodium diet

3. How Hyoscine Injection is given

This medicine is an injection which will be given to you by a doctor. Your doctor will determine the dose you require. It will be given under the skin or into a muscle.

Adults

Treatment of nausea (feeling sick), vomiting (being sick), vertigo (feeling dizzy and light headed), loss of balance and motion sickness:

- 200 micrograms as a single dose.

Preventing excessive production of saliva if you have been given a general anaesthetic:

- 200-600 micrograms given 30-60 minutes before the anaesthetic.

Children over 4 months of age

Treatment of nausea (feeling sick), vomiting (being sick), vertigo (feeling dizzy and light headed), loss of balance and motion sickness:

- 6 micrograms per kg of body weight as a single dose.

Preventing excessive production of saliva if you have been given a general anaesthetic:

- 15 micrograms per kg of body weight given 30-60 minutes before the anaesthetic.

Children (under 4 months)

Not recommended.

If you think you have been given too much Hyoscine Injection

This medicine is given to you by your doctor, so it is unlikely you will receive too much. Your doctor has information on how to recognise and treat an overdose.

If you experience any of the following please speak to your doctor or nurse immediately:

- dilated pupils
- a rapid heartbeat
- rapid breathing
- abnormally high temperature
- restlessness
- excitement
- confusion
- hallucinations (seeing or hearing things that aren't there)

4. Possible side effects

Stop taking your medicine and see a doctor immediately if you notice any of the following side effects as you may need urgent medical treatment:

- Serious allergic reaction, signs include skin rash, itching or hives, swelling of the face, lips, tongue or other parts of the body, difficulty breathing, feeling faint or dizzy. Cases including anaphylactic shock with a fatal outcome have been reported.
- collapse in hot weather due to decreased sweating

The most common side effects associated with hyoscine are:

- drowsiness
- dry mouth
- dizziness
- blurred vision
- difficulty passing water.

Other side effects include:

- headache
- loss of consciousness
- slow heart beat
- excitement
- psychotic disorder; this is an illness affecting mental health. You may experience delusions (believing things which are not true), hallucinations (seeing and possibly hearing or smelling things that are not really there) or lose touch with reality.
- confusion/delirium
- hallucinations
- dilation of the pupils
- sensitivity to light
- angle-closure glaucoma (red, painful eye)
- heart problems
- racing heart, and/or palpitations
- irregular heart beat
- flushing
- decrease in blood pressure
- constipation
- nausea
- vomiting
- difficulty in swallowing
- dyshidrosis: also known as ‘pompholyx’ or ‘dyshidrotic eczema’, is a skin condition which small, fluid-filled blisters appear on the fingers, palms of the hand, and sometimes on the soles of the feet. The blisters can be very itchy and painful and when they begin to heal and dry up, the skin can become cracked or scaly
- skin dryness
- pain at the site of injection (particularly after intramuscular use)
- thirst
- Neuroleptic malignant syndrome: this is a serious and potentially life-threatening condition. The signs may include a high fever, fast heartbeat, unstable blood pressure, sweating and tremor. Other signs are faster breathing, muscle stiffness, agitation and reduced consciousness. The level of an enzyme called creatine phosphokinase may be raised in your blood which suggests damage to muscles.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

5. How to store Hyoscine Injection

Keep this medicine out of the sight and reach of children.

You should not be given this medicine if it has passed the expiry date shown on the label. The expiry date refers to the last day of that month. The doctor or nurse will check this.

Protect from light. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Hyoscine Injection contains

The active ingredient is Hyoscine Hydrobromide 0.04% w/v.

The other ingredients are sodium chloride, dilute hydrobromic acid and water for injections.

What Hyoscine Injection looks like and contents of the pack

Hyoscine Injection is a clear, colourless solution supplied in clear glass 1ml ampoules. It is supplied in cartons containing ten ampoules.

Marketing Authorisation Holder and Manufacturer:

Martindale Pharma
Bampton Road,
Harold Hill,
Romford,
Essex,
RM3 8UG

Product License Number: PA 361/17/2

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