Cyclizine Lactate 50 mg/ml Solution for Injection

Cyclizine Lactate is the active ingredient in Cyclizine Injection, which belongs to a group of medicines called antihistamines which can be used especially to stop you feeling sick (nausea) or vomiting (sickening).

Cyclizine Injection can also be used to treat sickness.

This medicinal product is indicated in adults for:

1. Nausea and vomiting caused by narcotic analgesics and by general anaesthetics in the post-operative period.
2. Motion sickness when the oral route cannot be used.

Cyclizine Injection may be used by adults.

Cyclizine Injection may be used if you suffer from travel or motion sickness; nausea caused by severe anxiety or stress; vertigo (dizziness); vomiting properties of Cyclizine Injection may increase the toxicity of alcohol.

Side effects may include:

- skin rashes or itching;
- swelling of the face, lips or throat;
- itching or skin rashes;
- rash. More severe symptoms include swelling of the hands, arms or legs;
- skin rashes or itching;
- swelling of the face, lips, tongue and/or throat with difficulty swallowing;
- lack of coordination;
- unusual body movements, particularly of your hands, arms or legs;
- lack of balance and coordination, weakness, excessive excitement, impaired judgment, lack of coordination, muscle spasm, involuntary movements, convulsions, high temperature and difficulty breathing.

Possible side effects include:

- difficulty passing urine, drowsiness, dizziness, lack of balance and coordination, weakness;
- confusion, disorientation, impaired judgement, lack of balance and coordination, weakness;
- difficulty passing urine, drowsiness, dizziness, lack of balance and coordination, weakness; or if you have been given Cyclizine Injection;
- If you have been drinking alcohol. The anti- vomiting properties of Cyclizine Injection may increase the toxicity of alcohol.

Warnings and precautions

Talk to your doctor or nurse before you are given Cyclizine Injection if you:

- have been told your heart is not working properly (heart failure);
- have any liver problems;
- have been told you suffer from low blood pressure.

You should not be given this medicine:

- if you have ever had an allergic reaction to cyclizine or any of the other ingredients of this medicine (listed in section 6); (allergic reactions may be signs of an allergic reaction).
- if you have a history of porphyria;
- if you suffer from phaeochromocytoma (tumour of the medulla of the adrenal glands);
- if you have been told you suffer from high blood pressure;
- if you suffer from low blood pressure.
- if you have been told you have been drinking alcohol. The anti-vomiting properties of Cyclizine Injection may increase the toxicity of alcohol.

Side effects may include:

- skin rashes or itching;
- swelling of the face, lips or throat;
- difficulty in breathing or swallowing;
- swelling of the face, lips, tongue and/or throat with difficulty swallowing;
- lack of coordination;
- unusual body movements, particularly of your hands, arms or legs;
- lack of coordination;
- difficulty breathing.

Please refer to the Summary of Product Characteristics for full prescribing and other information.

Therapeutic indications

This medicinal product is indicated in adults for the prevention and treatment of nausea and vomiting caused by:

- Motion sickness when the oral route cannot be used;
- Nausea and vomiting caused by narcotic analgesics and by general anaesthetics in the post-operative period.

Vomiting associated with radiotherapy especially for breast cancer since cyclizine does not elevate prolactin levels.

Cyclizine Injection with alcohol

Alcohol should be avoided when you are being treated with Cyclizine Injection.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, you should not be given Cyclizine Injection.

Driving and using machines

You can drive while being treated with Cyclizine Injection but do not drive until you know how it affects you if you feel dizzy. If it affects you in this way, do not drive and use machines.

3. How to use Cyclizine Injection

You will be given Cyclizine Injection under supervision and your doctor will decide on a dose which is right for you.

Cyclizine Injection can be given as a slow injection into a vein (intravenously) or by injection into a muscle (intramuscularly).

The recommended dose for adults is 50 mg up to 3 times a day.

For prevention of sickness after a normal operation:

Your doctor will give the first dose of Cyclizine Injection by injection into a vein, approximately 20 minutes before the end of the operation.

If you use more Cyclizine Injection than you should

As this medicine is given to you by a doctor or nurse, it is very unlikely that an overdose will happen. Should an overdose occur, the doctor will treat any symptoms that follow. Symptoms of overdose include dry mouth, nose and throat, blurred vision, fast or irregular heartbeat, difficulty breathing, trouble urinating, dizziness, dizziness, lack of balance and coordination, weakness, excessive excitement, hallucinations, muscle spasm, involuntary movements, convulsions, high temperature and difficulty breathing.

Possible side effects include:

- skin rashes or itching;
- swelling of the face, lips or throat;
- difficulty in breathing or swallowing;
- swelling of the face, lips, tongue and/or throat with difficulty swallowing;
- lack of coordination;
- unusual body movements, particularly of your hands, arms or legs;
- lack of coordination.

The following information is intended for healthcare professionals only:

PREPARATION GUIDE:

Cyclizine Lactate 50 mg/ml Solution for Injection

Please refer to the Summary of Product Characteristics for full prescribing and other information.

Therapeutic indications

This medicinal product is indicated in adults for the prevention and treatment of nausea and vomiting caused by:

- Motion sickness when the oral route cannot be used;
- Nausea and vomiting caused by narcotic analgesics and by general anaesthetics in the post-operative period.

Vomiting associated with radiotherapy especially for breast cancer since cyclizine does not elevate prolactin levels.

Cyclizine Injection, by the intravenous route, is also indicated pre-operatively in patients undergoing emergency surgery in order to reduce the hazard of regurgitation and aspiration of gastric contents during induction of general anaesthesia.

Cyclizine Injection may be of value in relieving symptoms and relieving and other allergic reactions associated with Menière’s disease and other forms of vestibular disturbance when the oral route cannot be used.
Cyclizine Injection contains

- The active substance is cyclizine lactate. 1 ml of solution contains 50 mg cyclizine lactate.
- The other excipients are lactic acid and water for injections.

What Cyclizine Injection looks like and contents of the pack

Cyclizine Injection is a clear colourless solution free from visible particles supplied in 1 ml glass one-point-cut (OPC) ampoules. Each pack contains 5 or 10 ampoules.

Marketing Authorisation Holder

hameln pharmaceuticals Ltd
Gloucestor, GL3 4AG
United Kingdom

Manufactured by

HBM Pharma s.r.o
Sklabínska 30
836 80 Martin
Slovak Republic

The following information is intended for healthcare professionals only:

(Continued from overleaf)

- blurred vision or involuntary rolling of the eyes;
- paralysis especially in patient who are already partially paralyzed (halo-aneurysm);
- ringing in the ears;
- euphoria;
- headache;
- fast heartbeat, irregular heartbeat;
- dizziness or general feelings of weakness/tiredness;
- a dry mouth, nose or throat;
- heartburn (reflux);
- stomach pain;
- nausea;
- vomiting;
- diarrhoea;
- loss of appetite;
- difficulty in passing water;
- constipation;
- difficulty in sleeping;
- being confused, disoriented or unaware;
- dizziness;
- decreased consciousness/loss of consciousness;
- temporary difficulty in speaking;
- high blood pressure;
- low blood pressure;
- pins and needles;
- yellowing of the skin and the whites of your eyes (jaundice);
- a red or brownish patch which appears at the same spot each time you take the medicine;
- inflammation of the liver (hepatitis) or problems with the liver;
- injection site reactions such as redness, pain, swelling or blistering;
- sensations of heaviness, feeling cold or agitated or experiencing a decrease in blood pressure;
- reduced rate of breathing (apnoea);
- reduction in the production of a type of white blood cell making infection more likely (agranulocytosis).

Tell your doctor if you feel very tired, experience unexpected bruising or bleeding or more infections (e.g. colds and sore throats) than usual. Your doctor may decide to conduct tests on your blood periodically as a result of these symptoms.

The use of cyclizine, when given by an injection, has been linked to cases of temporary excessive muscle relaxation (paralysis). The onset of paralysis is usually within the first few minutes after you have been given this medicine and affects the arms and legs. The normal function of your muscles will return within hours of this medicine being stopped.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cyclizine Injection

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

Do not store above 25°C.

Keep the ampoule in the outer carton in order to protect from light.

Do not use this medicine after the expiry date which is stated on the carton and ampoule. The expiry date refers to the last day of that month.

Do not use this medicine if you notice any particles floating in it.

Do not use this medicine if the solution appears cloudy or coloured.

Do not throw away any medicines via wastewater. These measures will help protect the environment.

X

The following information is intended for healthcare professionals only:

(Continued from overleaf)

Cyclizine Lactate 50 mg/ml Solution for Injection

Cyclizine Injection is a clear colourless solution, free from visible particles.

pH 3.3-3.7

Administration

Intramuscular or intravenous use.

Dilution

This medicinal product can be diluted to a concentration of 5 mg/ml with glucose 50 mg/ml (5%), sodium chloride 9 mg/ml (0.9%) or water for injections.

The solution should be examined visually following dilution and immediately prior to administration and should not be used if any cloudiness or particulate matter is present.

6. Contents of the pack and other information

Shelf life

Unopened: 9 months

Diluted solution:

Chemical and physical in-use stability has been demonstrated 24 hours at 25°C for the diluted solution. From a microbiological point of view, the product should be used immediately and immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.