

Cyclizine Lactate 50 mg/ml Solution for Injection

cyclizine lactate

Read all of this leaflet carefully before you start using this medicine 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 pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

The name of this medicine is Cyclizine Lactate 50 mg/ml Solution for Injection but it will be referred to as Cyclizine Injection throughout the remainder of this leaflet.

What is in this leaflet

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

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

Cyclizine Injection contains the active ingredient cyclizine lactate, which belongs to a group of medicines called antihistamines which can be used to help stop you feeling sick (nausea) or being sick (vomiting).

Cyclizine Injection may be used by adults. Cyclizine Injection may be used if you suffer from travel or motion sickness; nausea caused by cancer treatment (radiotherapy) or other medicines; or if you have had an operation, as general anaesthetics can sometimes cause sickness.

Cyclizine Injection can also be used to treat sickness caused by some inner ear problems such as Meniere's disease.

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

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 include mild symptoms such as itching and/or rash. More severe symptoms include swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing);
- 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:

- suffer from an eye disease caused by a rise of pressure within the eye (glaucoma);
- suffer from urinary retention (experience difficulty passing urine);
- have an obstructive bowel condition;
- have any liver problems;
- suffer from phaeochromocytoma (tumour of the medulla of the adrenal glands);
- suffer from high blood pressure;
- have epilepsy;
- are a man and you suffer from an enlarged prostate gland (difficulty or slowness passing urine);
- have been told your heart is not working properly (heart failure);
- suffer from an inherited disorder which can lead to a sensitivity to sunlight (porphyria);
- suffer from low blood pressure.

Other medicines and Cyclizine Injection

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines especially the following:

- medicines for problems such as depression, anxiety or difficulty in sleeping;
- strong painkillers such as pethidine;
- any medicine which belongs to a group of medicines called anticholinergics.

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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 including:

- 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, ask your doctor for advice before you are given this medicine.

Driving and using machines

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

3. How Cyclizine Injection is given

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 three 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 receive 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 passing urine, drowsiness, dizziness, lack of balance and coordination, weakness, excitability, disorientation, impaired judgement, hallucinations, muscle spasm, involuntary movements, convulsions, high temperature and difficulty breathing.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor immediately, if you notice:

- itching or skin rashes;
- swelling of the face, lips or throat;
- difficulty in breathing or wheeziness.

These may be signs of an allergic reaction.

The following side effects are reported for with a not known frequency (frequency cannot be estimated from the available data)

Side effects may include:

- skin rashes or itching;
- muscle twitches, spasms or tremors;
- restlessness;

- Cyclizine, 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 vomiting and attacks of vertigo associated with Menière's disease and other forms of vestibular disturbance when the oral route cannot be used.

- decrease in muscle tone that can cause irregular body movements;
- unusual body movements, particularly of your hands, arms or legs;
- Unpleasant sensation or an overwhelming urge to move the legs (also called Restless Legs Syndrome);
- lack of coordination;
- blurred vision or involuntary rolling of the eyes;
- paralysis especially in patient who are already suffering from disorder of nerves and muscles;
- convulsions, seizures;
- nervousness;
- seeing or hearing things that are not really there (hallucinations);
- ringing in the ears;
- euphoria;
- headache;
- fast heartbeat, irregular heartbeat;
- drowsiness 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, disorientated 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, flushing, 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. 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 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 to slightly yellow 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

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Manufacturer

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For any information about this medicine, please contact the Marketing Authorisation Holder.

This leaflet was last revised in February 2024.

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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 to slightly yellow 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.

Shelf life

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.

If not used 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.