

Cyclizine Lactate 50 mg/ml Solution for Injection

Cyclizine lactate

Read all of this leaflet carefully before you start taking 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.

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 to use Cyclizine Injection
4. Possible side effects
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1. What Cyclizine Injection is and what it is used for.

The name of your medicine is Cyclizine Injection. 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**Do not take this medicine if:**

- If you are allergic to cyclizine lactate or any of the other ingredients of this medicine (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) (listed in section 6)
- 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 pharmacist before being treated with 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 (tumor 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 including those you have obtained without a prescription especially the following:

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

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

Pregnancy, breast-feeding and fertility

You should not be given Cyclizine Injection if you are pregnant or planning to become pregnant or if you are breast-feeding.

Driving and using machines

You can drive while being treated with cyclizine 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 or operate any machinery.

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 three times a day.

For prevention of sickness after a normal operation: your doctor will give the first dose of cyclizine by injection into a vein, approximately 20 minutes before the end of the operation.

The use of the injectable form of Cyclizine has been associated with cases of transient paralysis following administration of the medicine. The onset of paralysis is usually within minutes of administration, affects the limbs, and fully resolves within hours of discontinuation of the medicine.

If you receive more Cyclizine Injection than you should

As this medicine is given to you by a doctor, 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.

If you notice:

- Itching or skin rashes;
- Swelling of the face, lips or throat;
- Difficulty in breathing or wheeziness.

Tell your doctor immediately. These may be signs of an allergic reaction**Side effects may include:**

- skin rashes or itching;
- muscle twitches, spasms or tremors;
- restlessness;
- decrease in muscle tone that can cause irregular body movements;
- unusual body movements, particularly of your hands, arms or legs;
- 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, 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).

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

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:

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 Cyclizine Injection

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

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.

Cyclizine Injection will be stored by the hospital pharmacy before it is given to you. They will follow the instructions below.

Cyclizine Injection should be stored in a safe place below 25°C. Keep the ampoule in the outer carton in order to protect from light. For single use only. Discard any remaining contents immediately after use.

Do not use this medicine if you notice that the solution is discoloured or contains particles.

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 Cyclizine Injection contains**

Cyclizine Injection comes as a 1ml ampoule containing 50 mg of the active ingredient, cyclizine lactate, dissolved in water for Injections.

The injection also contains the inactive ingredient, lactic acid.

What Cyclizine Injection looks like and contents of the pack

Cyclizine Injection is a clear, colourless solution. Each pack contains 10 ampoules of 1ml

Marketing Authorisation Holder:

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

Manufacturer:

Macarthy's Laboratories Limited T/A Martindale Pharma.
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Romford, Essex
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United Kingdom

Product Licence No: PA 0549/033/001

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MARTINDALE PHARMA

DEVELOPMENT ARTWORK

Component Code: D04664

Prod: Cyclizine Cyclizine Lactate PIL
Ireland 50mg/ml Solution for Injection

Paper Size: 170 x 296mm

Version Control	Date	By
Version A:	14/12/18	SS
Version B:	20/12/18	SS
Version C:	07/01/19	SS
Version D:	07/01/19	SS
Version E:	09/01/19	SS
Version F:	10/06/19	SS
Version G:		
Version H:		
Version I:		
Version K:		
Version L:		
Version M:		
Version N:		
Version O:		

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