

## **PACKAGE LEAFLET**

## **Package leaflet: Information for the user**

### **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, pharmacist or nurse.
- 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

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

#### **1. What Cyclizine lactate Solution for injection is and what it is used for**

The name of your medicine is Cyclizine lactate Solution for injection. Cyclizine lactate Solution for 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 lactate Solution for injection may be used by adults.

Cyclizine lactate Solution for 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 lactate Solution for 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 use Cyclizine lactate Solution for injection**

##### **Do not use Cyclizine lactate Solution for injection if you:**

- ever had an allergic reaction to cyclizine 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);
- have been drinking alcohol. The anti-vomiting properties of Cyclizine lactate Solution for injection may increase the toxicity of alcohol.

#### **Warnings and precautions**

Talk to your doctor or pharmacist or nurse before using Cyclizine lactate Solution for 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 lactate Solution for injection**

Tell your doctor or pharmacist if you are taking 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.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines including those you have obtained without a prescription.

#### **Cyclizine lactate Solution for injection with food and drink**

**Alcohol** should be avoided when you are being treated with Cyclizine lactate Solution for injection.

#### **Pregnancy and breast-feeding**

You should not be given Cyclizine lactate Solution for 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 lactate 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 lactate Solution for injection**

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

Cyclizine lactate Solution for 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 lactate 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 use more Cyclizine lactate Solution for 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.**

The following side effects are reported for either compound 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;
- 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 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).

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 or pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the Yellow Card Scheme at:

[www.mhra.gov.uk/yellowcard](http://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 lactate Solution for injection**

Cyclizine lactate Solution for injection will be stored by the hospital pharmacy before it is given to you. They will follow the instructions below.

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

Protect from light, keep the ampoule in the outer carton.

The injection should not be used if there are any particles floating in it or after the “use by” date on the pack and the ampoule.

This medicine is for single use only. Discard any remaining contents immediately after use.

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 lactate Solution for injection contains**

- The active substance is cyclizine lactate. Each 1 mL of solution contains 50 mg cyclizine lactate.
- The other ingredients are lactic acid and water.

### **What Cyclizine lactate Solution for injection looks like and contents of the pack**

Cyclizine lactate Solution for injection is a clear, colourless solution for injection, supplied in 1 mL glass ampoules. It is available in packs of 5 ampoules.

### **Marketing Authorisation Holder**

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### **Manufacturer**

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