

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

### **Cyclizine Lactate 50 mg/ ml solution for Injection**

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

#### **1. What Cyclizine Lactate Injection is and what it is used for**

Cyclizine Lactate Injection contains the active substance 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 injection may be used by adults.

Cyclizine lactate 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 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 Lactate Injection**

##### **Do not use this medicine:**

- if you are allergic to cyclizine lactate or any of the other ingredients of this medicine (listed in section 6)
- if you have allergic reactions which 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 lactate injection may increase the toxicity of alcohol.

#### **Warning and precautions**

Talk to your doctor or nurse before you are given Cyclizine lactate 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 sensitivity to sunlight (porphyria)
- suffer from **low blood pressure**.

### **Other medicines and Cyclizine lactate 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 belong to a group of medicines called anticholinergics.

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

### **Cyclizine lactate Injection with food, drink and alcohol**

**Alcohol** should be avoided when you are being treated with Cyclizine lactate 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 lactate 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 or operate any machinery.

### **3. How Cyclizine lactate Injection will be given to you**

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

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

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

For single use only. Discard any unused product

Do not freeze

Cyclizine lactate Injection should be stored in a safe place below 25°C and protected from light. The injection should not be used if there are any particles floating in it or after the “EXP” date on the carton and label.

## **6. Content of the pack and other information**

### **What Cyclizine lactate Injection contains**

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

The injection also contains the inactive ingredient, (S)-lactic acid.

### **What Cyclizine lactate Injection looks like and contents of the pack**

Cyclizine lactate Injection is a Clear, colorless to slightly yellow solution. Each pack contains 5 or 10 ampoules. Not all pack sizes may be marketed.

## **Marketing Authorisation Holder and Manufacturer**

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