

Package leaflet: Information for the patient

Cyclizine hydrochloride Cipla 50 mg tablets

Cyclizine hydrochloride

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. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Cyclizine hydrochloride tablets are and what they are used for
2. What you need to know before you take Cyclizine hydrochloride tablets
3. How to take Cyclizine hydrochloride tablets
4. Possible side effects
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6. Contents of the pack and other information

1. What Cyclizine hydrochloride tablets are and what it is used for

Cyclizine hydrochloride tablets contains the active ingredient cyclizine hydrochloride 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 hydrochloride tablets may be used if you suffer from travel or motion sickness; nausea caused by cancer treatment (radiography) or other medicines; or if you have had an operation, as general anaesthetics can sometimes cause sickness.

Cyclizine hydrochloride tablets 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 take Cyclizine hydrochloride tablets

Do not take Cyclizine hydrochloride tablets

- If you are allergic to cyclizine or any 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.

Warnings and precautions:

Take special care with this medicine and tell your doctor or pharmacist if you:

- suffer from an eye disease caused by a rise of pressure within the eye (glaucoma);
- have an obstructive bowel condition;
- have any liver problems;
- have fits (epilepsy);

- are a man and you suffer from an enlarged prostate gland (difficulty or slowness in 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).

Children and adolescents (below 6 years)

Do not give this medicine to children age below 6 years.

Other medicines and Cyclizine hydrochloride tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including those taken without prescription.

Tell your doctor or pharmacist if you are taking especially the following medicines:

- 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 hydrochloride tablets with food and alcohol

Alcohol should be avoided when you are taking Cyclizine hydrochloride tablets.

Pregnancy and breast-feeding

You should not take Cyclizine hydrochloride tablets if you are pregnant or planning to become pregnant unless your doctor feels it is necessary. You should not take Cyclizine hydrochloride tablets if you are breast-feeding.

Driving and using machinery

You can drive while taking Cyclizine hydrochloride tablets but do not drive until you know how the tablets affect you. Cyclizine hydrochloride tablets may make you feel dizzy. If they affect you in this way, do not drive or operate any machinery.

Cyclizine hydrochloride tablets contains lactose monohydrate

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product

3. How to take Cyclizine hydrochloride tablets

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Adults and children over 12 years

The usual dose is one tablet up to three times daily.

Children from 6 to 12 years

The usual dose is half a tablet up to three times a day.

Children under 6 years

Do not give this medicine to children under the age of 6.

The tablets should be swallowed with a little water.

If you take more Cyclizine hydrochloride tablets than you should

If you accidentally take too many Cyclizine hydrochloride tablets than you have been told to take, tell your doctor at once or contact your doctor or nearest hospital emergency department **immediately**. Remember to take this leaflet and/or the package with you to show the doctor what you have taken.

If you forget to take Cyclizine hydrochloride tablets

If you forget to take a dose, just take the next dose at the usual time, DO NOT take a double dose.

Do not stop taking your tablets, even if you are feeling well, unless your doctor tells you.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Cyclizine hydrochloride tablets 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.

Stop taking the tablets and tell your doctor immediately. These may be signs of an allergic reaction.

Other side effects include:

- skin rashes or itching;
- drowsiness;
- headache;
- a dry mouth, nose or throat;
- blurred vision;
- fast heartbeat;
- difficulty in passing urine;
- constipation;
- restlessness;
- nervousness;
- difficulty in sleeping;
- seeing or hearing things that are not really there (hallucinations);
- A spasmodic movement of the eyeballs into a fixed position abnormal physical weakness or lack of energy
- difficulty catching one's breath despite not having exercised
- decrease in muscle tone;
- unusual body movements, particularly of your hands, arms or legs;
- muscle twitches, spasms or tremors;
- fits and seizures;
- being confused, disorientated or unaware;
- dizziness;
- decreased consciousness;
- temporary difficulty in speaking;
- high 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; 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

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 hydrochloride tablets

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 label after “EXP”. The expiry date refers to the last day of that month.

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.

This medicinal product does not require any special temperature storage conditions.

6. Contents of the pack and other information

What Cyclizine hydrochloride Tablets contain

The active substance is Cyclizine hydrochloride. Each tablet contains 50 mg of cyclizine hydrochloride.

The other ingredients are:
Lactose Monohydrate (200 Mesh)

Maize Starch

Sodium Starch Glycolate (Primojel) (Type A)

Povidone (PVP K-30)

Colloidal Anhydrous Silica

Magnesium Stearate

What Cyclizine hydrochloride tablets look like and the contents of the pack

Cyclizine hydrochloride 50 mg tablets are white to off white, circular shaped, flat bevelled uncoated tablet with central break line on one side and plain on other.

The tablet can be divided into two halves.

Cyclizine hydrochloride 50 mg tablet is available in blister packs of 100 tablets.

Marketing Authorisation Holder:

Cipla (EU) Limited

Hillbrow House, Hillbrow Road, Esher, Surrey, KT10 9NW, United Kingdom

Manufacturer

Cipla (EU) Ltd, 4th Floor, 1 Kingdom Street, London, W2 6BY, United Kingdom

This medicinal product is authorised in the Member States of the EEA under the following names:

United Kingdom: Cyclizine Hydrochloride 50mg Tablet

Ireland: Cyclizine Hydrochloride Cipla 50mg Tablets

Malta: Cyclizine Hydrochloride Cipla 50mg Tablets

This leaflet was last revised in 11/2014