

Package leaflet: Information for the patient

Cyclizine Hydrochloride 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Cyclizine Hydrochloride 50 mg Tablets. It will be referred to as Cyclizine Hydrochloride Tablets for ease hereafter.

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
5. How to store Cyclizine Hydrochloride Tablets
6. Contents of the pack and other information

1. WHAT CYCLIZINE HYDROCHLORIDE TABLETS ARE AND WHAT THEY ARE USED FOR

Cyclizine Hydrochloride Tablets contain the active substance 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 by adults and children aged 6 years and over. 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 hydrochloride 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)
- if you have been drinking alcohol. The anti-vomiting properties of cyclizine may increase the toxicity of alcohol.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Cyclizine Hydrochloride Tablets 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).

Other medicines and Cyclizine Hydrochloride Tablets

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 belong to a group of medicines called anticholinergics.

Cyclizine Hydrochloride Tablets with food and drink

Alcohol should be avoided when you are taking Cyclizine Hydrochloride Tablets.

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 or pharmacist for advice before taking this medicine.

Driving and using machines

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 contain lactose.

If you have been told that you have **intolerance to some sugars**, talk to your doctor before taking these tablets.

3. HOW TO TAKE CYCLIZINE HYDROCHLORIDE TABLETS

Always take this medicine exactly as your doctor or pharmacist has told you.

Check with your doctor, pharmacist or nurse if you are not sure.

Adults

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

Use in children and adolescents

Children over 12 years

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

Children from 6 to 12 years

The recommended dose is half a tablet up to three times a day. The tablet can be divided into equal doses along the line scored on one side of the tablet.

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

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.

If you take more Cyclizine Hydrochloride Tablets than you should, 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 to make up for a forgotten tablet.

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

stop taking this medicine and tell your doctor immediately. These may be signs of an allergic reaction.

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

- skin rashes or itching
- drowsiness
- lack of coordination
- headache
- a dry mouth, nose or throat
- blurred vision
- involuntary rolling of the eyes

- fast heartbeat
- irregular heartbeat
- difficulty in passing water
- constipation
- heartburn (reflux)
- feeling sick
- being sick
- diarrhoea
- stomach pain
- loss of appetite
- restlessness
- nervousness
- euphoria
- difficulty in sleeping
- ringing in the ears
- seeing or hearing things that are not really there (hallucinations)
- decrease in muscle tone
- unusual body movements, particularly of your hands, arms or legs
- muscle twitches, spasms or tremors
- seizures
- being confused, disorientated or unaware
- dizziness
- feeling weak
- decreased 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
- an increased sensitivity to sunlight (photosensitivity)
- 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).
- unpleasant sensation or an overwhelming urge to move the legs (also called Restless Legs Syndrome).

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.

If any of the side effects becomes severe or you notice any side effects not listed in this leaflet please **tell your doctor or pharmacist immediately.**

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 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 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 carton and label after EXP. The expiry date refers to the last day of that month.

Store this medicine in a safe place below 25°C.

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 Hydrochloride Tablets contains

Each tablet contains 50 mg of the active ingredient, cyclizine hydrochloride. The other ingredients include: lactose, potato starch, acacia and magnesium stearate.

What Cyclizine Hydrochloride Tablets look like and contents of the pack

Cyclizine Hydrochloride Tablets are white with a single score line and the marking “T4A” on the same side. They are available in bottles of 100 tablets.

Marketing Authorisation Holder

Amdipharm UK Limited,
Dashwood House,
69 Old Broad Street, London,
EC2M 1QS, United Kingdom

Manufacturer:

CENEXI SAS,
52 Rue Marcel et Jacques Gaucher, 94120, Fontenay sous Bois, France

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