



AMDIPHARM

Cyclizine Hydrochloride 50 mg Tablets

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 symptoms 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
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

The name of your medicine is Cyclizine Hydrochloride 50 mg Tablets. Cyclizine Hydrochloride Tablets contain 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 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 this medicine if:

- you have 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).
- you have been drinking alcohol. The anti-vomiting properties of cyclizine may increase the toxicity of alcohol.

Cyclizine Hydrochloride Tablets should not be used in children under the age of 6 years.

Warnings and precautions

Take special care with this medicine and tell your doctor or pharmacist 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).

Cyclizine Hydrochloride Tablets and other medicines

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.

Taking Cyclizine Hydrochloride Tablets with food and drink

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.

Important information about some of the ingredients of Cyclizine Hydrochloride Tablets. 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 Cyclizine Hydrochloride Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist 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.

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 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 your medicine

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

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;
- lack of coordination;
- headache;
- a dry mouth, nose or throat;
- blurred vision;
- 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).

Rare side effects include:

- 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.

Very rare side effects include:

- 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

website: www.mhra.gov.uk/yellowcard.

5. HOW TO STORE CYCLIZINE HYDROCHLORIDE TABLETS

Store your tablets in a safe place below 25°C. Do not take any tablets after the "use by" date shown on the pack.

KEEP ALL MEDICINES OUT OF THE SIGHT AND REACH OF CHILDREN

Return any unused tablets to your pharmacist.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Cyclizine Hydrochloride Tablets contain

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 the 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 and Manufacturer responsible for batch release:

Amdipharm UK Limited,
Capital House, 85 King William Street,
London EC4N 7BL, UK

Alternative Site for batch release:

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

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