PACKAGE LEAFLET

#### Package leaflet: Information for the patient

## Cyclizine Hydrochloride 50mg 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, or 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.

#### 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
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#### 1. What Cyclizine Hydrochloride Tablets are and what they are used for

The name of your medicine is Cyclizine Hydrochloride 50mg Tablets.

Cyclizine Hydrochloride Tablets contains the active substance Cyclizine hydrochloride, which belongs to a group of medicines known as antihistamines. Antihistamines help to prevent feelings of sickness (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 for the following conditions:-

- travel and motion sickness
- post-operative nausea and vomiting, as general anesthetics can sometimes cause sickness
- nausea associated with cancer treatment (radiography) or other medicines
- treatment of sickness due to inner ear problems, such as Meniere's disease

You must talk to a doctor if you do not feel better or if you feel worse.

#### 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 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).
- if you have been drinking alcohol. The anti-vomiting properties of Cyclizine hydrochloride may increase the toxicity of alcohol.

## Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking Cyclizine hydrochloride Tablets:

## Take special care with Cyclizine Hydrochloride Tablets, 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 conditions
- have any liver problems
- suffer from epilepsy
- are male and have an enlarged prostate gland (difficulty and slowness passing urine)
- have been told your heart is not working properly (heart failure)
- have an inherited disorder which can lead to a sensitivity of sunlight called porphyria
- have been told by your doctor that you have an intolerance to some sugars
- suffer from urinary retention (experience difficulty passing urine)
- suffer from phaeochromocytoma (tumour of the medulla of the adrenal glands)
- suffer from high blood pressure

#### Children

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

**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 obtained without a prescription. In particular, tell your doctor about 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.
- drugs which can damage the ear (ototoxic) for example aminoglycoside antibacterials

#### Cyclizine Hydrochloride Tablets with alcohol

You should avoid taking alcohol whilst you are on Cyclizine Hydrochloride Tablets.

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

If you are pregnant, think you may be pregnant or are planning to have a baby,ask your doctor or pharmacist for advice before taking this medicine.

Do not take these tablets if you are breast-feeding.

#### **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 by your doctor that you have an intolerance to some sugars, contact 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 or pharmacist if you are not sure.

The recommended dose is as follows:

Adults and children over 12 years: The usual dose is one tablet (50mg) up to three times daily.

*Children from 6 to 12 years:* The usual dose is half a tablet (25mg) up to three times a day.

*Children under 6 years:* Do not give this medicine to children under the age of 6.

For preventing motion sickness, take the recommended dose 1-2 hours before travelling.

*Method of administration* Swallow these tablets 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 heart beat, difficulty passing urine, drowsiness, dizziness, lack of balance and coordination, weakness, excitability, disorientation, impaired judgement, hallucinations, muscle spasms, involuntary movements, convulsion, high temperature and difficulty breathing.

If you take more 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 HydrochlorideTablets

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 dose.

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

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

# Stop taking the tablets and tell your doctor immediately if you experience any of the following symptoms:

- itching or skin rashes
- swelling of the face, lips or throat
- difficulty in breathing or wheeziness.

## 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
- irregular heart beat
- difficulty in passing water
- constipation
- restlessness

- nervousness
- difficulty in sleeping
- seeing or hearing things that are not really there (hallucinations)
- lack of coordination
- heart burn (reflux)
- feeling sick
- being sick
- diarrhoea
- stomach pain
- loss of appetite
- euphoria
- ringing in the ears
- Unpleasant sensation or an overwhelming urge to move the legs (also called Restless Legs Syndrome).

## **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, disoriented 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
- a increase in sensitivity to sunlight (photosensitivity)
- inflammation of 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 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 Website: www.mhra.gov.uk/yellowcard. 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 and carton. 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.

#### 6. Contents of the pack and other information

#### What Cyclizine Hydrochloride Tablets contain

- The active substance is cyclizine hydrochloride.
- Each tablet contains 50mg of the active ingredient, cyclizine hydrochloride.
- The other ingredients are maize starch, lactose, povidone and magnesium stearate.

#### What Cyclizine Hydrochloride Tablets look like and contents of the pack

Cyclizine Hydrochloride Tablets are circular, white tablets with a breakline on one side and plain on the reverse.

These tablets are available in blisters of 1, 10, 28, 30, 40, 50, 84, 100 and 500 tablets. They are also available in a bottle containing 100 tablets.

Not all pack sizes may be marketed.

#### Marketing Authorisation Holder and Manufacturer

Brown & Burk UK Limited 5, Marryat Close Hounslow West Middlesex TW4 5DQ UK.

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