

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

### **Betahistine dihydrochloride 8 mg Tablets Betahistine dihydrochloride 16 mg Tablets (Betahistine dihydrochloride)**

**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 Betahistine Tablets are and what they are used for
2. What you need to know before you take Betahistine Tablets
3. How to take Betahistine Tablets
4. Possible side effects
5. How to store Betahistine Tablets
6. Contents of the pack and other information

#### **1. What Betahistine Tablets are and what they are used for**

The name of your medicine is Betahistine Tablets. This medicine is called a histamine analogue. It is used to treat the following symptoms of Ménière's disease:

- Dizziness (vertigo)
- Ringing in the ears (tinnitus)
- Hearing loss.

This medicine works by improving blood flow in the inner ear. This lowers the build up of pressure.

#### **2. What you need to know before you take Betahistine Tablets**

##### **Do not take Betahistine Tablets:**

- If you are allergic to betahistine or any of the other ingredients of this medicine (listed in section 6).
- If you have high blood pressure due to an adrenal tumour (phaeochromocytoma).

If any of the above applies to you, do not take this medicine and talk to your doctor.

##### **Warnings and precautions:**

Talk to your doctor or pharmacist before taking Betahistine Tablets if:

- You have a stomach ulcer
- You have asthma
- You are pregnant or planning to become pregnant
- You are breast-feeding.

Your doctor will tell you whether it is safe for you to start taking this medicine.

Your doctor may also want to monitor your asthma while you take Betahistine Tablets.

##### **Other medicines and Betahistine Tablets**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes herbal medicines.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Anti-histamines – these may (in theory) lower the effect of Betahistine Tablets. Also, Betahistine may lower the effect of anti-histamines.
- Monoamine-oxidase inhibitors (MAOIs) – used to treat depression or Parkinson's disease. These may increase the exposure of Betahistine.

### **Betahistine Tablets with food and drink**

You can take Betahistine Tablets with or without food. However, betahistine can cause mild stomach problems (listed in section 4). Taking betahistine with food can help reduce stomach problems.

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

Do not take Betahistine Tablets if you are pregnant unless your doctor has decided that it is absolutely necessary. Ask your doctor for advice.

Do not breast-feed while using Betahistine Tablets unless instructed by your doctor. It is not known if Betahistine passes into breast milk.

### **Driving and using machines**

Betahistine Tablets are not likely to affect your ability to drive or use tools or machinery. However, remember that diseases for which you are being treated with Betahistine (vertigo, tinnitus and hearing loss associated with Meniere's syndrome) can make you feel dizzy or be sick, and can affect your ability to drive or use machines.

## **3. How to take Betahistine 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 usual starting dose is 8-16 mg three times a day.
- Your dose should not exceed 48 mg daily.

Betahistine Tablets are not recommended for those under 18 years old.

### **Method of administration**

- Swallow the tablets with water.
- Preferably take the tablet with a meal.

### **If you take more Betahistine Tablets than you should**

If you or someone else takes too much Betahistine Tablets (an overdose), talk to a doctor or go to a hospital straight away. Take the medicine pack with you.

### **If you forget to take Betahistine Tablets**

If you miss a tablet, wait until the next dose is due. Do not take a double dose to make up for a forgotten dose.

### **How to stop taking Betahistine Tablets**

Keep taking your tablets until your doctor tells you to stop.

Even when you start feeling better, your doctor may want you to carry on taking the tablets for some time to make sure that the medicine has worked completely.

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

## **4. Possible side effects**

Like all medicines, Betahistine Tablets can cause side effects, although not everybody gets them.

**The following serious side effects may occur during treatment with Betahistine Tablets:**

Allergic reactions such as:

- Swelling of your face, lips, tongue or neck. This may cause difficulty breathing.
- A red skin rash, inflamed itchy skin.

If any of these side effects occur, you should stop treatment immediately and contact your doctor.

**Common side effects (may affect up to 1 in 10 people):**

Nausea, indigestion, headaches.

**Other side effects**

Itching, rash, hives, mild gastric complaints such as vomiting, stomach pain and bloating. Taking Betahistine Tablets with food can help reduce any stomach problems.

**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: HPRA Pharmacovigilance, Website: [www.hpra.ie](http://www.hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Betahistine Tablets**

- Keep this medicine out of the sight and reach of children.
- Do not use the tablets after the expiry date, which is printed on the carton and blister pack after 'EXP'. The expiry date refers to the last day of that month.
- Store in the original pack in order to protect from moisture.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

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

**What Betahistine dihydrochloride Tablets contain**

The active substance is betahistine dihydrochloride.

8 mg: Each tablet contains 8 mg of betahistine dihydrochloride.

16 mg: Each tablet contains 16 mg of betahistine dihydrochloride.

The other ingredients are: Microcrystalline cellulose, mannitol, colloidal anhydrous silica, anhydrous citric acid and talc.

**What Betahistine dihydrochloride Tablets look like and contents of the pack**

**Betahistine dihydrochloride 8 mg Tablets** are white to off-white, round, flat, bevel-edged tablets debossed '8' on one side and 'B' on other side with a diameter of 7 mm.

**Betahistine dihydrochloride 16 mg Tablets** are white to off-white, round, biconvex, scored tablets debossed '16/B' on one side and plain on other side with a diameter of 8.5 mm. The tablet can be divided into equal doses.

**Betahistine dihydrochloride Tablets** are available in blister packs of 84 and 120 tablets.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder**

Azure Pharmaceuticals Ltd, 12 Hamilton Drive, The Rock Road, Blackrock, Co. Louth, A91 T997, Ireland.

**Manufacturer**

Meiji Pharma Spain, S.A., Avda. de Madrid, 94, Alcalá de Henares, 28802 Madrid, Spain.

**This leaflet was last revised in October 2021**