

**PACKAGE LEAFLET: INFORMATION FOR THE USER****Betahistine Dihydrochloride 8mg and 16mg 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 dihydrochloride Tablets is and what it is used for
2. What you need to know before you take Betahistine dihydrochloride Tablets
3. How to take Betahistine dihydrochloride Tablets
4. Possible side effects
5. How to store Betahistine dihydrochloride Tablets
6. Contents of the pack and other information

**1. What Betahistine dihydrochloride Tablets is and what it is used for**

These tablets contain Betahistine dihydrochloride.

They are used to treat vertigo, tinnitus (ringing in the ears) and hearing loss associated with Meniere's disease.

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 dihydrochloride tablets****Do not take Betahistine dihydrochloride Tablets:**

- if you are allergic (hypersensitive) to Betahistine dihydrochloride or any of the other ingredients of Betahistine dihydrochloride Tablets (listed in section 6). The symptoms of an allergic reaction include itching, nettle rash, wheezing or swelling of the hands, throat, mouth or eyelids
- if you have a phaeochromocytoma (high blood pressure due to adrenal tumour).

If you think any of the above points apply to you, do not take the tablets. Talk to your doctor first and follow the advice given.

**Warnings and precautions**

Talk to your doctor or pharmacist before taking Betahistine tablets

- if you have a stomach ulcer
- if you suffer from 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 dihydrochloride 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:

- Antihistamines - these may (in theory) lower the effect of Betahistine tablets. Also, Betahistine tablets 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 Dihydrochloride

**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.

**Betahistine dihydrochloride Tablets contains lactose**

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

Information on sodium content:

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially "sodium-free".

**3. How to take Betahistine dihydrochloride tablets**

Always take Betahistine dihydrochloride tablets exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Swallow the tablets with water and always take with or after meal.

**Usual dose for adults and the elderly:**

The usual starting dose of Betahistine dihydrochloride 16mg three times a day.

After you have been taking treatment for a while your doctor may change the dose to between 24 and 48mg a day.

Keep taking your tablets. The tablets can take a while to start to work.

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

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

An overdose of this medicine may be dangerous. If you accidentally take too many tablets tell your doctor or go to the nearest hospital casualty department immediately. The symptoms of a betahistine dihydrochloride tablets overdose are nausea, vomiting, digestion problems, coordination problems and – with higher doses – fits.

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

If you forget to take a dose at the right time take it as soon as you remember and if it is

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FLAT DIMENSION = 130 x 430mm

FOLDED DIMENSION = 130 x 27mm

almost time for your next dose, wait until that is due then go on as before. Do not take a double dose to make up for the forgotten dose.

#### **If you stop taking Betahistine dihydrochloride Tablets**

Do not stop taking your Betahistine dihydrochloride tablet without talking to your doctor.

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 product, ask your doctor or pharmacist.

#### **4. Possible side effects**

Like all medicines, these tablets can cause side effects, although not everybody gets them

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

- Allergic reactions such as: Swelling of your face, lips, tongue or neck. This may cause difficulty in 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 and headache**

##### **Other side effects**

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

**If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.**

##### **Reporting of side effects:**

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card scheme Website: [www.mhra.gov.uk/yellowcard](http://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 Betahistine tablets**

Keep out of the sight and reach of children.

- Do not store above 30°C.
- Do not put them into another container as they might get mixed up.
- Do not use Betahistine dihydrochloride Tablets after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

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

##### **What Betahistine Tablets contains**

The active substance is betahistine dihydrochloride (8mg or 16mg). The other ingredients are lactose monohydrate, maize starch, microcrystalline cellulose, citric acid anhydrous (for pH adjustment), crospovidone, povidone, Pregelatinised Maize Starch and sodium stearyl fumarate. Betahistine dihydrochloride tablets are gluten free.

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

Betahistine tablets are round white tablets. The 8mg tablets have 'R3' stamped on one side with a scoreline on the other and the 16mg tablets have 'R4' stamped on one side with a scoreline on the other.

Betahistine 8mg and 16mg tablets are available in packs of 84, 100 and 120 Tablets. Not all pack sizes may be marketed.

##### **Marketing Authorisation Holder and Manufacturer**

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**Betahistine 8mg Tablets; PL 17907/0686**

**Betahistine 16mg tablets; PL 17907/0687**

**This leaflet was last revised in April 2022**

**To request a copy of this leaflet in Braille, large print or audio format, please contact the marketing authorisation holder at the address (or telephone, fax, email) above.**