

PACKAGE LEAFLET: INFORMATION FOR THE USER

BETAHISTINE DIHYDROCHLORIDE 8 mg and 16 mg TABLETS

The name of your medicine is Betahistine Dihydrochloride Tablets, which will be called Betahistine Tablets throughout this leaflet.

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Betahistine Tablets are and what they are used for
2. Before you take Betahistine Tablets
3. How to take Betahistine Tablets
4. Possible side effects
5. How to store Betahistine Tablets
6. Further information

1. WHAT BETAHISTINE TABLETS ARE AND WHAT THEY ARE USED FOR

Betahistine Tablets contain 8 mg or 16 mg of the active ingredient betahistine dihydrochloride. Betahistine Tablets belong to a group of medicines known as histamine analogues, which means it closely resembles histamine – a chemical found naturally in the body.

Betahistine works by improving blood flow in the inner ear, which reduces the build up of pressure. It is this pressure in the ear that causes vertigo (dizziness), tinnitus (ringing in the ears), and hearing loss suffered by people with Ménière's disease.

2. BEFORE YOU TAKE BETAHISTINE TABLETS

Do not take Betahistine Tablets if you

- are allergic (hypersensitive) to betahistine or any of the other ingredients of Betahistine Tablets (see list of ingredients in Section 6). An allergic reaction may include rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue
- have a phaeochromocytoma (a very rare tumour of the adrenal gland)

Take special care with Betahistine Tablets if you have

- had a peptic ulcer. Your doctor will monitor you closely during your treatment.
- asthma. Your doctor will monitor you closely during your treatment.

Taking other medicines

Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines, including medicines obtained without a prescription.

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 Tablets may lower the effect of anti-histamines.
- Monoamine-oxidase inhibitors (MAOIs) - used to treat depression or Parkinson's disease. These may increase the blood level of Betahistine Tablets.

Pregnancy and breast-feeding

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

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

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Betahistine Tablets are not likely to affect your ability to drive or operate machinery, although the vertigo, tinnitus and hearing loss associated with Ménière's syndrome (for which you are taking betahistine) can make you feel dizzy or be sick, and may affect your ability to drive or use machines. Make sure you know how this medicine affects you before you drive or operate machines.

Important information about some of the ingredients of Betahistine Tablets

Betahistine Tablets contain **lactose**. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. HOW TO TAKE BETAHISTINE TABLETS

Always take Betahistine Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The tablets should be swallowed preferably with a drink of water, and are best taken with or after a meal. The usual dose is:

Adults (including the elderly)

The usual starting dose is 16 mg three times daily.

The usual dose after this is 24-48 mg daily (as three divided doses).

Children

Betahistine Tablets are not recommended for use in children below 18 years.

If you take more Betahistine Tablets than you should

It is important to stick to the dose on the label of your medicine. If you or someone else takes too many Betahistine Tablets all together, contact your doctor, pharmacist or hospital emergency department immediately. Always take any tablets left over with you and also the box, as this will allow easier identification of the medicine.

If you forget to take Betahistine Tablets

If you forget to take a dose, take it as soon as you remember. Do not take a double dose to make up for a forgotten dose if it is almost time for your next dose.

If you stop taking Betahistine Tablets

Do not stop taking your medicine without talking to your doctor first, even if you feel better.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Betahistine Tablets can cause side effects, although not everybody gets them. All medicines can cause allergic reactions, although serious allergic reactions are very rare.

Tell your doctor straight away if you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body).

The following side effects have been reported at the frequencies shown:

Common (affecting less than 1 in 10 patients)

- feeling sick
- indigestion
- headache

Frequency not known

- itching, skin rash, or hives (red and sometimes itchy bumps on your skin)
- mild gastric complaints such as being sick, stomach pain, swollen belly or bloating. Taking the medicine with food 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, please tell your doctor or pharmacist.

5. HOW TO STORE BETAHISTINE TABLETS

Betahistine Tablets should be kept out of the reach and sight of children.

Do not store above 25°C.

Store in the original package.

Do not use Betahistine 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.

6. FURTHER INFORMATION

What Betahistine Tablets contain:

The active substance is betahistine dihydrochloride.

The other ingredients are: povidone K90, microcrystalline cellulose, lactose, colloidal anhydrous silica, crospovidone and stearic acid.

What Betahistine Tablets look like and contents of the pack

Betahistine Tablets are white to almost white tablets.

Betahistine 8mg Tablets are imprinted with 'B8' on one side.

Betahistine 16mg Tablets are imprinted with 'B16' on one side.

The tablets are packed in blister strips.

Each carton of 8 mg Betahistine dihydrochloride tablets contains 84 or 120 tablets.

Each carton of 16 mg Betahistine dihydrochloride tablets contains 60 or 84 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and manufacturer

Teva UK Limited, Eastbourne, BN22 9AG

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