



Package leaflet:
Information for the user

Betahistine 8 mg tablets
Betahistine 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 signs of illness 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 is and what it is used for
2. What you need to know before you take Betahistine
3. How to take Betahistine
4. Possible side effects
5. How to store Betahistine
6. Contents of the pack and other information

1. What Betahistine is and what it is used for

Betahistine is a type of medicine called a "histamine analogue".

Betahistine is used for:

Ménière's disease – the signs of this include:

- feeling dizzy (vertigo)
- ringing in the ears (tinnitus)
- hearing loss or hearing difficulty

How this medicine works

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

Do not take Betahistine

- if you are allergic to betahistine or to any of the other ingredients of this medicine (listed in section 6)
- if you have a pheochromocytoma, a rare tumour of the adrenal gland

Warnings and precautions

Talk to your doctor or pharmacist before taking Betahistine.

- if you have or have had a stomach ulcer (peptic ulcer)
- if you have asthma
- if you have nettle rash, skin rash or a cold in the nose caused by an allergy, since these complaints may be exacerbated.
- if you have low blood pressure
- Betahistine dihydrochloride is not the appropriate treatment for the following forms of vertigo:
 - attacks of benign positional vertigo,
 - dizziness related to a disease of the central nervous system.
- if you are pregnant or planning to become pregnant
- if you are breast-feeding

If you suffer from any of the above conditions, consult your doctor about whether you may take Betahistine tablets.

These groups of patients should be monitored by a doctor during treatment.

Use in Children and adolescents

Betahistine is not recommended for use in children and adolescents (below 18 years of age)

Other medicines and Betahistine

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

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

Anti-histamines – This is because in theory betahistine may not work properly. 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.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Betahistine.

Taking Betahistine with food and drink

Betahistine can be taken 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, breast-feeding and fertility

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

It is not known whether betahistine dihydrochloride affects the unborn child.

Do not take betahistine dihydrochloride 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 dihydrochloride tablets unless instructed by your doctor. It is not known if betahistine passes into breast milk.

Driving and using machines

Betahistine is not likely to affect your ability to drive or use tools or machinery.

However, remember that the disease for which you are being treated with Betahistine (Ménière's disease) can make you feel dizzy or sick, and can affect your ability to drive and use machines.

3. How to take Betahistine

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- Your doctor will adjust your dose, depending on your progress.
- Keep taking your medicine. The medicine can take a while to start to work.

How to take Betahistine

- Swallow the tablets with water.
- Take the tablet with or after a meal. However, Betahistine can cause mild stomach problems (listed in Section 4). Taking Betahistine with food can help reduce stomach problems.

How much Betahistine to take

Always follow your doctor's instructions because your doctor might adjust your dose.

The recommended dose is:

Adults

The recommended dose is 24 mg to 48 mg per day. 8 mg tablets: one or two tablets three times a day.

16 mg tablets: half or one tablet three times a day. 24 mg tablets: 1 tablet two times per day. This form of the medication is used when you need 48 mg of betahistine per day.

Dosage

Daily dose should not exceed 48 mg.

In some cases, improvement does not begin to become apparent until two weeks after starting treatment. The optimal result is obtained after several months of treatment.

 If you take more than one tablet each day, spread your tablets evenly over the day. For example, take one tablet in the morning, one at midday and one in the evening.

Try to take your tablet at the same time each day. This will make sure that there is a steady amount of the medicine in your body. Taking at the same time will also help you remember to take your tablets. Betahistine is not recommended for use in children.

If you take more Betahistine than you should

If you or someone else takes too many Betahistine tablets (an overdose), you may feel sick (nauseous), sleepy or have stomach pain. It can also appear, acceleration of the heartbeat (tachycardia), low blood pressure (hypotension), shortness of breath with a feeling of suffocation (bronchospasm), accumulation of fluids in the tissues (edema). Seizures can occur after taking very high doses.

Symptomatic treatment is recommended as there is no specific antidote.

Talk to a doctor or go to a hospital immediately. Take the Betahistine pack with you.

If you forget to take Betahistine

Wait until you have to take your next dose. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Betahistine

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, this medicine can cause side effects, although not everybody gets them. Very few adverse effects have been reported with betahistine.

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

Allergic reactions:

- a red or lumpy skin rash or inflamed itchy skin
- swelling of your face, lips, tongue or neck
- a drop in your blood pressure
- loss of consciousness
- difficulty breathing

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

Other side effects include:

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

- feeling sick (nausea)
- indigestion (dyspepsia)
- headache.

The following undesirable effects have been reported spontaneously during post-marketing use and in scientific literature. A frequency cannot be estimated from the available data and is therefore classified as "not known"

Blood and lymphatic system disorders

Not known: Thrombocytopenia.

Immune system disorders:

Not known: hypersensitivity reactions, e.g. anaphylaxis.

Other side effects that have been reported with the use of betahistine

Mild stomach problems such as being sick (gastralgia, vomiting), stomach pain, dry mouth, diarrhea, stomach swelling (abdominal distension) and bloating. Taking betahistine with food can help reduce stomach problems.

Skin and subcutaneous tissue disorders

Not known: cutaneous and subcutaneous hypersensitivity reactions, in particular angioneurotic oedema, urticarial, rash, and pruritus.

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

The United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

5. How to store Betahistine

Keep this medicine out of the sight and reach of children.

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the label, carton, bottle after (EXP). 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 Betahistine contains

- The active substance is betahistine dihydrochloride. Each tablet contains 8 mg betahistine dihydrochloride. Each tablet contains 16 mg betahistine dihydrochloride.
- The other ingredients are microcrystalline cellulose, mannitol, povidone, crospovidone, citric acid, colloidal anhydrous silica, talc and stearic acid.

What Betahistine looks like and the contents of the pack

Tablet.

Betahistine 8 mg tablets

White to off-white round, flat uncoated tablets debossed with 'X' on one side and '87' on the other side.

Betahistine 16 mg tablets

White to off-white round uncoated tablets debossed with 'X' and a break line on one side and '88' on the other side. The tablet can be divided into equal doses.

Betahistine Tablets are available in:

Blisters of Polyamide/ Aluminium/ PVC/ Aluminium:

8 mg: 10, 20, 30, 50, 60, 84, 90, 100 & 120 tablets

16 mg: 10, 20, 30, 60, 84 & 90 tablets

White opaque round HDPE bottle with polypropylene closure containing cotton coil: 30 and 1000 tablets.

Not all pack sizes may be marketed

Marketing Authorisation Holder

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Manufacturer

APL Swift Services (Malta) Limited
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