

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Betahistine Dihydrochloride 8mg and 16mg Tablets

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 histamine analogue medicine. These work by reducing the pressure in the inner ear.

They are used to treat:

- Vertigo
- Tinnitus (ringing in the ears)
Hearing loss associated with Meniere's disease

2. What you need to know before you take Betahistine

Do not take Betahistine if:

- You are allergic to Betahistine dihydrochloride or any of the other ingredients of this medicine (listed in section 6)
- You have phaeochromocytoma (high blood pressure due to an adrenal tumour)

Warnings and precautions

Talk to your doctor before taking Betahistine if:

- You have a peptic (stomach) ulcer
- You suffer from bronchial asthma

Other medicines and Betahistine

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those obtained without a prescription. This includes herbal medicines.

Medicines which **may interact with or be affected by** Betahistine:

- Antihistamines, used to treat allergic conditions
- Monoamine-oxidase inhibitors (MAOIs) used to treat depression, such as selegiline

Taking Betahistine with food and drink

These tablets should preferably be taken with meals.

Pregnancy and breast-feeding

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

Pregnancy

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

Breast-feeding

Do not breast-feed while using Betahistine unless instructed by your doctor as it is not known if Betahistine passes into breast milk. The benefits to the mother should be weighed against the potential risks for the child.

Driving and using machines

Betahistine should not affect the ability to drive and use machines. However, if any effects are experienced, do not drive or operate machinery.

Betahistine contains lactose

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

3. How to take Betahistine

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

- These tablets are to be taken orally, preferably with meals.
- The score line is only there to help you break the tablet for ease of swallowing and not to divide into equal doses.

Adults and the elderly

- The initial dose is 16mg three times daily.
- Maintenance doses are generally between 24-48mg daily.

Use in children

Not recommended for use in children below 18 years of age.

If you take more Betahistine than you should

If you accidentally take too many tablets, contact your doctor or nearest hospital emergency department **immediately** for advice. Remember to take this leaflet or any remaining tablets with you. **Symptoms of overdose include:** feeling sick (nausea), sleepiness or drowsiness (somnolence), stomach pain, fits (convulsions), breathing (pulmonary) or heart (cardiac) complications.

If you forget to take Betahistine

Take it as soon as you remember, unless it is nearly time for your next dose. If you miss a dose, **do not** take a double dose to make up for a forgotten dose.

If you stop taking Betahistine

It is important that you keep taking Betahistine for as long as your doctor has told you to.

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 can cause side effects, although not everybody gets them

Seek medical advice immediately if you develop the following symptoms:

- Allergic reactions: swelling of the face, throat or tongue
- Difficulty in breathing or dizziness (anaphylaxis)
- Swelling of the deeper layers of the skin caused by a build-up of fluid (angioedema)

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

- Feeling sick (nausea)
- Indigestion (dyspepsia)
- Headache

Other side effects (frequency not known)

- Mild gastric complaints such as being sick (vomiting), stomach pain, bloating. Taking Betahistine with meals can help to reduce these symptoms
- Skin rashes, including with the formation of wheals (urticaria)
- Severe itching (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 via the Yellow Card scheme at: 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

- Keep this medicine out of the sight and reach of children.
- Do not use Betahistine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.
- Do not store above 30°C. Store in the original package.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information**What Betahistine contains:**

- Each 8mg tablet contains betahistine dihydrochloride 8mg
- Each 16mg tablet contains betahistine dihydrochloride 16mg

The other ingredients are: lactose, maize starch, microcrystalline cellulose, citric acid, crospovidone, povidone K25 and sodium stearyl fumarate.
Betahistine dihydrochloride tablets are gluten free.

What Betahistine looks like and contents of the pack

- Betahistine 8mg are flat, white tablets with a bevelled edge, marked 'R3' on one side with a score-line on the reverse
- Betahistine 16mg are flat, white tablets with a bevelled edge, marked 'R4' on one side with a score-line on the reverse

Betahistine is available in:

Betahistine Tablets are available in blister packs of 84, 100 or 120 tablets.

Not all pack sizes may be marketed.

Product Licence Numbers:

- Betahistine 8mg Tablets: PL 11311/0677
- Betahistine 16mg Tablets: PL 11311/0678

Marketing Authorisation Holder:

Tillomed Laboratories Limited
220 Butterfield
Great Marlings
Luton
LU2 8DL
United Kingdom

Manufacturer:

Wave Pharma Limited
4th Floor Cavendish House
369 Burnt Oak
Edgware
Middlesex
HA85AW
United Kingdom

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