

Package leaflet: Information for the user

Betahistine dihydrochloride 8mg Tablets

Betahistine dihydrochloride 16mg Tablets

Betahistine dihydrochloride 24mg 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.
- This medicine is available under the above product names but will be called 'Betahistine Tablets' throughout the package leaflet.

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

Betahistine dihydrochloride, the active substance of Betahistine Tablets, is similar to histamine, a substance which is found naturally in the human body. Betahistine works by reducing signals in the balance centre of the brain which lead to dizziness.

Betahistine Tablets are used for the treatment of Menière's syndrome, symptoms of which may include dizziness (often associated with feeling sick and / or being sick), ringing in the ear (tinnitus) and hearing loss.

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

Do not take Betahistine Tablets

- if you are allergic to betahistine dihydrochloride or any of the other ingredients of this medicine (listed in section 6).
- if you suffer from a tumour of the adrenal gland (phaeochromocytoma).

Warnings and precautions

Talk to your doctor or pharmacist before taking Betahistine Tablets

- if you suffer from ulcers of the stomach or intestine.
- if you suffer from a chronic disease of the respiratory tract (bronchial asthma).
- if you suffer from hives, skin rashes, or allergic rhinitis - your symptoms may get worse when taking betahistine.
- if you have very low blood pressure.

- if you are taking at the same time other medicines used to treat allergies or colds - so called antihistamines (see also section 'Other medicines and Betahistine Tablets').

Other medicines and Betahistine Tablets

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

If Betahistine Tablets are taken at the same time with certain medicines for the treatment of allergies or colds (antihistamines) the effects of both medicines may be reduced. If you are currently taking an antihistamine, the dose of this medicinal product must be slowly reduced over about 6 days before you can start taking Betahistine Tablets.

Betahistine Tablets with food and drink

This medicinal product sometimes causes stomach disorders; see section 4 'Possible side effects'. The likelihood of these happening may be reduced by taking Betahistine Tablets with, or shortly after food.

Pregnancy, breast-feeding and fertility

Betahistine Tablets should only be taken during pregnancy or breast feeding if your doctor feels it is essential for you. There is not enough animal and human data available for use in pregnancy and lactation. You should discuss this with your doctor if you are, or might be pregnant, or if you are breast feeding.

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

Driving and using machines

There is no experience whether this medicinal product impairs the ability to drive and use machines.

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 usual dose is 24 mg - 48 mg betahistine daily, divided into 3 equal doses.

Daily dose should not exceed 48 mg and your doctor or pharmacist will advise you how many tablets to take.

The tablets should be taken, with a glass of water, during or after meals.

Your doctor will tell you how long to take the medicine. It is usually a long term treatment and lasts several months as the tablets may take a while to start to work.

Use in children and adolescents

Betahistine Tablets should not be used by children and adolescents below the age of 18 years. There is no information or experience on such use.

If you take more Betahistine Tablets than you should

If you take more tablets than you should, the following symptoms may occur due to overdose: headache, redness of the face, low blood pressure, faster heartbeat, breathing difficulties due to constriction of the lungs (bronchial asthma), and swelling of the surface of the upper airways due to water retention (Quincke's oedema).

You must get medical advice urgently if you experience any of these events. The doctor will provide suitable treatment. Always take the medicinal product package with you when getting such advice.

If you forget to take Betahistine Tablets

If you forget to take a dose, just miss out that dose. Take the next dose the next time you would usually take it. Do not take a double dose to make up for a forgotten dose.

If you stop taking Betahistine Tablets

Do not stop taking Betahistine Tablets before your doctor tells you to.

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

4. Possible side effects

Like all medicines, this medicine 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 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 (at least 1 in 100 and less than 1 in 10 patients):

- Nausea, indigestion, headaches.

Other side effects:

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

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. 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 this medicine after the expiry date which is stated on the carton and on the blister package after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 to protect the environment.

6. Contents of the pack and other information

What Betahistine Tablets contain

The active substance is betahistine dihydrochloride.

One 8 mg tablet contains 8 mg betahistine dihydrochloride.
One 16 mg tablet contains 16 mg betahistine dihydrochloride.
One 24 mg tablet contains 24 mg betahistine dihydrochloride.

The other ingredients are: lactose monohydrate, maize starch, microcrystalline cellulose (E 460), citric acid anhydrous (E 330), povidone K 25 (E 1201), crospovidone type A (E 1202), and hydrogenated vegetable oil.

What Betahistine Tablets look like and contents of the pack

Betahistine 8mg Tablets are white, flat, round tablets with bevelled edges, score line on one side, diameter 6.5 mm. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Betahistine 16mg Tablets are white, flat, round tablets with bevelled edges. The tablets have a break-line and the inscription "BH" on one side of the score and "16" on the other side of the score, both markings on the same side of the tablet. The tablet diameter is 9.0 mm. The tablet can be divided into equal halves.

Betahistine 24mg Tablets are white, flat, round tablets with bevelled edges. The tablets have a break-line and the inscription "BH" on one side of the score and "24" on the other side of the score, both markings on the same side of the tablet. The tablet diameter is 10.0 mm. The tablet can be divided into equal halves.

Packed in blister packs containing 14, 20, 24, 28, 30, 48, 50, 60, 84, 90, 96, or 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Morningside Healthcare Ltd
115 Narborough Road
Leicester
LE3 0PA

Manufacturers

Farmaceutisch Analytisch Laboratorium (FAL) Duiven BV
Dijkgraaf 30, Duiven
6921 RL
The Netherlands

Medochemie Limited
Facility A-Z, Miichael Erakleous
Ayios Athanassios Industrial Area
Limassol
Cyprus

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