

Package leaflet: Information for the user
Betahistine dihydrochloride 8 mg tablets
Betahistine dihydrochloride 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, pharmacist or nurse.
- 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, pharmacist or nurse. 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

Betahistine is a histamine analogue medicine that is used to treat symptoms of Ménière's syndrome such as dizziness (vertigo), ringing in the ears (tinnitus), loss of hearing and nausea.

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 (see section 6, Contents of the pack and other information).
- if you have high blood pressure due to adrenal tumour (phaeochromocytoma), a rare tumour of the adrenal gland.

Warning and precautions

- if you have 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

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

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

Other medicines and Betahistine dihydrochloride tablets

An interaction means that the medicines or substances can affect the way each other works or the side effects when both are being taken at the same time.

So far no interactions of betahistine with other medicines have been observed.

It is possible that betahistine may influence the effect of antihistamines. Antihistamines are medicines that are used in particular for the treatment of allergies such as hay fever and for car sickness. Consult your doctor or pharmacist if you are using antihistamines (medicines against allergies) at the same time.

Monoamine-oxidase inhibitors (MAOIs)- used to treat depression or Parkinson's disease may increase the exposure of Betahistine **dihydrochloride** tablet.

Inform your doctor or your pharmacist if you are using (or have recently used) other medicines. This also applies for other medicines that are available without prescription.

Betahistine dihydrochloride tablets with food and drink

You can take Betahistine with or after food.

Pregnancy, breast-feeding and fertility

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 dihydrochloride 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 dihydrochloride tablets (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 monohydrate

This medicine contains 50 mg lactose monohydrate for 8 mg strength and 100 mg lactose monohydrate for 16 mg strength. Patients with rare hereditary abnormalities of galactose tolerance, individuals with Lapp lactase deficiency or glucose-galactose malabsorption should not use this medication. Tell your doctor if you know you have a sugar intolerance.

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.

Betahistine dihydrochloride tablets are not recommended for use in children and adolescents below 18 years of ages, as there are no data on efficacy and safety in these age groups.

The usual dose is:

Adults

The usual starting dose is one to two 8 mg tablets or a half to one 16 mg tablet three times a day. The maintenance dose is usually in the range 24-48 mg daily.

It may take a couple of weeks before you notice any improvement.

How to use

Swallow the tablets with water. Take the tablet with or after food. Take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Initial oral treatment is 8 to 16 mg three times daily, taken preferably with meals.

Maintenance doses are generally in the range 24 - 48 mg daily. Daily dose should not exceed 48 mg. Dosage can be adjusted to suit individual patient needs. Sometimes improvement could be observed only after a couple of weeks of treatment.

There is no data available for patients with hepatic impairment.

There is no data available for patients with renal impairment.

There is limited data in the elderly, betahistine should be used with caution in this population.

Use in children and adolescents (6 to 18 years old)

Not recommended for use in children and adolescents below age 18 due to lack of data on safety and efficacy.

If you take more betahistine dihydrochloride tablets than you should

If you have taken more than the prescribed dose, consult your doctor.

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

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 dihydrochloride tablets

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 side effects may occur:

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 (may affect up to 1 in 10 people):

Headache, occasional drowsiness, nausea, indigestion, mild gastric complaints such as vomiting, stomach pain and bloating. Taking Betahistine with food can help reduce any stomach problems.

Not known (frequency cannot be estimated from the available data)

Itching, rash, hives, abnormal heart beat (palpitations), bronchospasms may occur in patients with bronchial asthma

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

For UK- You can also report side effects directly via the via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

For Ireland -You can also report side effects directly via
HPRA Pharmacovigilance,
Earlsfort Terrace, IRL - Dublin 2;
Tel: +353 1 6764971; Fax: +353 1 6762517.
Website: www.hpra.ie;
E-mail: medsafety@hpra.ie.

5. How to store Betahistine dihydrochloride tablets

- Store below 30 ° C.
- Store your tablets in the original package in order to protect from moisture.
- Keep out of the reach and sight of children.
- Do not take the tablets after the expiry date which is clearly stated on the package. The expiry date refers to the last day of the 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. Contents of the pack and other information

What Betahistine dihydrochloride tablets contains

The active substance is betahistine dihydrochloride.
Each tablet contains 8 mg or 16 mg betahistine dihydrochloride.
The tablets contain the following non-active ingredients:
Lactose monohydrate, povidone K25, anhydrous citric acid Maize starch, microcrystalline cellulose , crospovidone , hydrogenated vegetable oil

What Betahistine dihydrochloride tablets look like and contents of the pack

Betahistine dihydrochloride 8 mg tablets

This medicinal product is presented as white, round, flat tablets with bevelled edges with the inscription 'BE' on one side and a breakline on the other side.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Betahistine dihydrochloride 16 mg tablets

This medicinal product is presented as white, round, flat tablets with bevelled edges with the inscription 'BF' on one side and a breakline on the other side.

The tablet can be divide into two equal halves.

For 8mg the tablets are packaged in blister strips (PVC/PVdC-aluminium).

Pack size of 14, 20, 30, 50, 60, 84, 90 and 120 tablets.

For 16mg the tablets are packaged in blister strips (PVC/PVdC-aluminium)

Pack size of 14, 20, 30, 60, 84, 90 and 120 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Accord Healthcare Limited,

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United Kingdom

Manufacturer

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3526 KV Utrecht,
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This medicinal product is authorised in the member states of the EEA under the following names.

Country	Proposed invented name
NL	Betahistine 2HCL Accord 8 / 16 mg Tabletten
FR	Betahistine Accord 8 mg Comprimés
IE	Betahistine dihydrochloride 8/16mg Tablets
IT	Betahistine dihydrochloride Accord Healthcare 8 / 16 mg Compresse
PL	Betahistine dihydrochloride Accord
UK	Betahistine dihydrochloride 8/16 mg Tablets

This leaflet was last revised in 12/2019.