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 are and what they are 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 (listed in section 6).
- if you have high blood pressure due to adrenal tumour (phaeochromocytoma), a rare tumour of the adrenal gland.

Warning and precautions
- if have a stomach ulcer (peptic ulcer) or if you have had a stomach ulcer in the past
- if you have asthma
- 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.

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

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 tablets.

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. However, Betahistine dihydrochloride tablets may cause mild stomach upset (see section 4). Taking it with food can reduce stomach complaints.

Pregnancy, breast-feeding and fertility
Do not take betahistine 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 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
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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.

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 (under 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:

If you have an allergic reaction, stop taking Betahistine dihydrochloride tablets and go straight to your doctor or hospital.

Symptoms of an allergy can be:

- A red or lumpy skin rash or inflamed itchy skin
- Swelling of your face, lips, tongue or neck
- Drop in blood pressure
- Loss of consciousness
- Breathing difficulties

Other side effects

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

Headache, nausea, indigestion

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

- Mild stomach problems such as feeling sick (vomiting), stomach ache, swelling of the stomach and bloating. Taking Betahistine with food can help reduce stomach problems
- Swelling of the deeper layers of the skin caused by a build-up of fluid (angioedema)
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via
HPRA Pharmacovigilance,
Website: www.hpra.ie.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Betahistine dihydrochloride 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 label and carton. The expiry date refers to the last day of that month.
- Store below 30°C.
- Store your tablets in the original package in order to protect from moisture.
- Do not throw away any medicines via wastewater. 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 dihydrochloride tablets contains

The active substance is betahistine dihydrochloride.
Each tablet contain 8 mg betahistine dihydrochloride.
Each tablet contain 16 mg betahistine dihydrochloride.

The other ingredients are: lactose monohydrate, povidone K25, anhydrous citric acid Maize starch, microcrystalline cellulose , crospovidone and 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 Ireland Limited
Euro House
Euro Business Park
Little Island
Cork T45 K857
Ireland

Manufacturer

Accord Healthcare Polska Sp.z o.o.,
ul. Lutomierska 50,95-200 Pabianice, Poland

Accord Healthcare B.V.,
Winthontlaan 200,
3526 KV Utrecht,
The Netherlands

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Name of the Member State	**Name of the medicine**
The Netherlands	Betahistine 2HCL Accord 8 / 16 mg Tabletten
France	Betahistine Accord 8 mg Comprimes
Ireland	Betahistine dihydrochloride 8/16mg Tablets
Italy	Betahistine dihydrochloride Accord Healthcare 8 / 16 mg Compresse
Poland	Betahistine dihydrochloride Accord
United Kingdom (Northern Ireland)	Betahistine dihydrochloride 8/16 mg Tablets

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