

BESTEDY 24

Betahistine Dihydrochloride Tablets BP 24mg

Betahistine Dihydrochloride (24mg)

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What BESTEDY is used for

BESTEDY is used for:

Ménière's disease – the signs of this include:

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

Symptomatic treatment of vestibular vertigo (an inner ear disorder)

How BESTEDY works

Betahistine dihydrochloride is thought to work by improving blood flow in the inner ear, which reduces the build-up of pressure.

Before you use BESTEDY

- When you must not use it

- if you are allergic to betahistine or to any of the other ingredients of this medicine.
- if you have a pheochromocytoma, a rare tumour of the adrenal gland.

Pregnancy and lactation

Do not take BESTEDY if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take BESTEDY if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

If you have any of the below conditions, consult your doctor about whether you may take Betahistine tablets. These groups of patients should be monitored by a doctor during treatment.

- stomach ulcer (peptic ulcer)

- asthma
- nettle rash, skin rash or a cold in the nose caused by an allergy, since these complaints may be exacerbated.
- low blood pressure

Children

Bestedy 24 Betahistine Dihydrochloride Tablets is not recommended for use in children under the age of 18 years.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Tell your doctor if you are particularly taking:

- Anti-histamines – This is because in theory betahistine may not work properly. Also, betahistine may lower the effect of antihistamines.
- 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.

How to use BESTEDY

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

The dosage for adults is 48mg divided over the day.

24 mg tablets

1 tablet

2 times/day

The dosage should be individually adapted according to the response. Improvement can sometimes only be observed after a couple of weeks of

treatment. The best results are sometimes obtained after a few months. There are indications that treatment from the onset of the disease prevents the progression of the disease and/or the loss of hearing in later phases of the disease.

- Swallow the tablets with water.
- Take the tablet with or after a meal.

Betahistine can cause mild stomach problems. Taking Betahistine with food can help reduce stomach problems.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking BESTEDY for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you or someone else takes too many Betahistine tablets (an overdose), you may feel sick (nauseous), sleepy, stomach pain, vomit or seizure. Talk to a doctor or go to a hospital immediately. Take the Betahistine pack with you.

While you are using it**- Things you must do**

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking BESTEDY.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give BESTEDY to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of**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.

Side effects

Like all medicines, BESTEDY can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

The undesirable effects have been experienced with the below indicated frequencies in betahistine-treated patients: very common; common; uncommon; rare; very rare; and not known.

Gastrointestinal disorders

Common: nausea and dyspepsia (indigestion)

Nervous system disorders:

Common: headache

Immune system disorders

Hypersensitivity (allergic) reactions (such as anaphylaxis) may be reported.

Gastrointestinal disorders

Mild gastric complaints (e.g. vomiting, gastrointestinal pain, abdominal distension and bloating) may be observed. These can normally be dealt with by taking the dose during meals or by lowering the dose.

Skin and subcutaneous tissue disorders

Cutaneous (skin) and sub cutaneous (tissue under the skin), hypersensitivity (allergic) reactions may be reported, in particular angioneurotic oedema (sudden onset of face, neck or limb swelling), urticaria (hives), rash and pruritus (itchiness).

You may report any side effects or adverse drug reactions directly to The National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.moh.gov.my (Consumers → Reporting → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of BESTEDY**- Storage**

Keep out of the reach and sight of children.

Do not store above 30°C. Protect from light and moisture.

- Disposal

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.

Product Description**- What it looks like**

White to off-white round uncoated tablets debossed with 'X' and a break line on one side and '89' on the other side.

- Ingredients

- Active ingredient

Betahistine dihydrochloride.

- Inactive ingredients

Cellulose microcrystalline (Avicel pH 101), Mannitol, Povidone, Crospovidone, Citric acid, anhydrous, Cellulose microcrystalline (Avicel PH 112), Silica colloidal anhydrous, Talc and Stearic acid.

- MAL number:

MAL20126018AZ

Manufacturer

Aurobindo Pharma Limited,
Unit-III, Survey No: 313 314,
Bachupally Village, Bachupally Mandal,
Medchal-Malkajgiri District, Hyderabad,
Telangana, 500090, India.

Product Registration Holder

UNIMED SDN BHD,
No. 53, Jalan Tembaga, SD 5/2B, Bandar
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Malaysia.

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