

BETAQUIL Tablets®

Betahistine Dihydrochloride (8 mg, 16 mg)

Consumer Medication Information Leaflet (RiMUP)

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What is BETAQUIL used for

The active substance of BETAQUIL is Betahistine Dihydrochloride.

Betahistine is a type of medicine called a “histamine analogue”.

Betahistine is used for:
Ménière’s disease – the signs of this include:

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

How BETAQUIL 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 BETAQUIL

-When you must not use it

Do not take BETAQUIL tablet if

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

Pregnancy and lactation:

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

Do not take BETAQUIL 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 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 tablets.

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

Children

Betahistine is not recommended for those under 18 years old.

-Taking other medications

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.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

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.

Hypersensitivity to any component of Betahistine Dihydrochloride Tablets.

How to use BETAQUIL

-How much to use

Adults: 24-48 mg in divided doses daily.

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.

However, 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 BETAQUIL 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 or have stomach pain. Talk to a doctor or go to a hospital immediately. Take the Betahistine pack with you.

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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 BETAQUIL.

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 BETAQUIL 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, Betahistine Dihydrochloride Tablets can cause side effects although not everybody gets them.

STOP taking Betahistine Dihydrochloride Tablets and see your doctor or nearest hospital casualty department IMMEDIATELY if you experience:

- an allergic reaction. Symptoms of an allergic reaction include; skin rashes, inflamed itchy skin, swelling of the lips, face, throat or tongue, difficulty breathing or swallowing.

Other side effects are:

- feeling sick (nausea)
- headaches
- indigestion (dyspepsia)

- mild gastric complaints such as being sick (vomiting)
- abdominal pain and bloating
- stomach upsets
- itching and skin rashes
- Swelling of the skin (angioneurotic oedema)
- Hives

Taking this medicine with food can help reduce any stomach problems.

If any side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

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.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of BETAQUIL

-Storage

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

Keep this medicine out of the reach and sight of children.

Do not use this medicine after the expiry date which is stated on the blister and carton after (EXP). The expiry date refers to the last day of that month.

-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

Betahistine Dihydrochloride Tablets BP 8 mg: White to off-white round, flat uncoated tablets debossed with 'X' on one side and '87' on the other side.

Betahistine Dihydrochloride Tablets BP 16 mg: White to off-white round uncoated tablets debossed with 'X' and a break line on one side and '88' on the other side.

-Ingredients

- Active ingredient(s): Betahistine dihydrochloride.
- Inactive ingredient(s): 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

8mg: MAL18056069AZ

16mg: MAL18056068AZ

Manufacturer

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

Product Registration Holder

Healol Pharmaceuticals Sdn. Bhd, 74-3, Jalan Wangsa Delima 6, KLSC Wangsa Maju, 53300 Kuala Lumpur.

Date of revision

26/05/2023

Serial Number

NPRA(R2/2)230525/1075