

Consumer Medication Information Leaflet (RiMUP)

BETASERC® TABLETS

Betahistine dihydrochloride (16mg, 24mg)

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What Betaserc® is used for

Betaserc® is used to treat Ménière's syndrome that has the following symptoms

- Dizziness (vertigo) with nausea and vomiting
- Ringing in ears (tinnitus)
- Hearing loss

Betaserc® is also used to treat vestibular vertigo.

How Betaserc® works

Betaserc® contains betahistine which improves blood flow in the ear that lowers the buildup of pressure.

Before you use Betaserc®

- When you must not use it

Do not take Betaserc® if:

- You are allergic (hypersensitive) to betahistine or any of the other ingredients of Betaserc®
- You have high blood pressure due to adrenal tumor.
(Pheochromocytoma)

Do not use Betaserc® if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Betaserc®.

- Before you start to use it

Talk to your doctor or pharmacist before taking Betaserc® if you suffer from any medical conditions or illnesses, in particular:

- if you have stomach ulcer
- if you have asthma

Your doctor may want to monitor your asthma while you take Betaserc®.

- Taking other medicines

It is particularly important to tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This also concerns medicines obtained without a prescription including herbal medicines. Tell your doctor or pharmacist if you are taking any of the following medicines:

- antihistamines (drug commonly used in allergies)
- Monoamine-oxidase inhibitors (MAOIs) (drug used to treat depression or Parkinson's disease)

How to use Betaserc®

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully.

The usual adult dose is 24-48mg divided over the day.

Betaserc® 16mg Tablet: ½ - 1 tablet three times daily

Betaserc® 24mg Tablet: 1 tablet twice daily

Betaserc® is not recommended under 18 years old.

- When to use it

Use as directed by your doctor or pharmacist.

Betaserc® may be taken with or without food.

- How long to use it

Continue taking Betaserc® for as long as your doctor or pharmacist recommends.

Even when you start feeling better, your doctor may want you to continue taking the medicine for some time to make sure that the medicine has worked completely.

- If you forget to use it

Do not take a double dose to make up for the forgotten dose. Take the next dose at your regular time on the next day. If you are worried about this, talk to your doctor or pharmacist.

- If you use too much (overdose)

If you take more Betaserc® than you should stop taking Betaserc® and talk to a doctor or pharmacist.

Symptoms of overdose include nausea, somnolence and abdominal pain, seizures, lungs and heart complications.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

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

- Things to be careful of

Pregnancy and breast feeding

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

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- Do not take Betaserc® if you are breast feeding or plan to breastfeed your baby, because it known that the medicine passes into breast milk.

Side effects

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

The following serious side effects may occur during treatment with Betaserc®:

Vomiting, gastrointestinal pain, bloating and allergic reactions such as

- swelling of face, lips, tongue or neck. This may cause difficulty in breathing.
- Hives, skin rash, itchy skin

Common (may affect more than 1 in 100 people):

Nausea, indigestion, headache

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

Storage and Disposal of Betaserc®

- Storage

Keep this medicine out of the sight and reach of children. Do not use Betaserc® after the expiry date which is stated on the carton and the blister after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C.

- Disposal

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 protect the environment.

Product Description

- What it looks like

Betaserc® 16mg Tablet is a round, biconvex, white tablet with “267” imprinted. The tablet can be divided into equal halves.

Betaserc® 24mg Tablet is a round, biconvex, white to almost white tablet with “289” imprinted. The tablet can be divided into equal halves.

Betaserc® is available in cartons of 20's, 50's and 100's. Not all pack sizes are marketed.

- Ingredients

- Active ingredient(s)

Betahistine dihydrochloride

- Inactive ingredients

Microcrystalline cellulose, mannitol (E421), citric acid monohydrate, colloidal anhydrous silica, L-Cysteine hydrochloride monohydrate, propyl gallate and talc

- MAL number: Betaserc®

16mg Tablet:
MAL19972468ACZ

Betaserc® 24mg Tablet:
MAL07061394ACZ

Manufacturer

Mylan Laboratories SAS
01400 Châtillon-sur-Chalaronne
France

Product Registration Holder

Abbott Laboratories (M) Sdn. Bhd.
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