

Consumer Medication Information Leaflet (RiMUP)

BETASERC[®] OD MODIFIED RELEASE FILM COATED TABLET

Betahistine dihydrochloride 48mg

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What Betaserc[®] OD is used for

Betaserc[®] OD 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[®] OD is also used to treat vestibular vertigo.

How Betaserc[®] OD works

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

Before you use Betaserc[®] OD

- When you must not use it

Do not take Betaserc[®] OD if:

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

Do not use Betaserc[®] OD if any of the above applies to you. If you are not sure, talk to your doctor or

pharmacist before taking Betaserc[®] OD

- Before you start to use it

Talk to your doctor or pharmacist before taking Betaserc[®] OD 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[®] OD.

- 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[®] OD

- How much to use

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

The usual adult dose is 1 tablet of 48mg once daily

Betaserc[®] OD is not recommended under 18 years old.

- When to use it

Use as directed by your doctor or pharmacist.

Betaserc[®] OD may be taken with or without food.

- How long to use it

Continue taking Betaserc[®] OD 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[®] OD than you should stop taking Betaserc[®] OD 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

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- Do not take Betaserc[®] OD if you are pregnant, trying to get pregnant or think you may be pregnant.
- Do not take Betaserc[®] OD 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[®] OD can cause side effects, although not everybody gets them.

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

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

Storage and Disposal of Betaserc[®] OD

- Storage

Keep this medicine out of the sight and reach of children. Do not use Betaserc[®] OD 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[®] OD Modified Release (48mg betahistine hydrochloride) Film Coated Tablet is a round, round biconvex tablet, yellow, coated and smooth on both sides

Betaserc[®] OD is available in cartons of 30's, 60's and 90's. Not all pack sizes are marketed.

- Ingredients

- Active ingredient(s)
Betahistine dihydrochloride

- Inactive ingredients
Microcrystalline cellulose, mannitol (E421), citric acid monohydrate, citric acid monohydrate, co-processed polyvinyl acetate and povidone polymer, talc, opadry 03F180011 White and opadry II 85F220031 Yellow

- MAL number:

Betaserc[®] OD Modified Release (48mg betahistine dihydrochloride) Film Coated Tablet
MALXXXXXXXX

Manufacturer

Abbott Laboratories de Mèxico, S.A de C.V.
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Product Registration Holder

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