

Betaserc[®]

8 mg, 16 mg, 24 mg tablets

8, 16 or 24 mg betahistine dihydrochloride



Read this entire leaflet carefully before you start taking this medicine.

Keep this leaflet. You may need to read it again. If you have questions not answered by this pamphlet, please ask your doctor or pharmacist. This medicine has been prescribed to you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

Betaserc 8 mg is a round, flat, white tablet with beveled edges. The tablet is engraved with the insignia S on one side and the number 256 on the other. This tablet is for oral administration (to be taken by mouth) and contains 8 mg of betahistine dihydrochloride.

Betaserc 16 mg is a round, biconvex, scored, white tablet with beveled edges and the insignia S engraved on one side. On the other side, the tablet is scored and the number 267 is engraved on either side of the score line. This tablet is for oral administration (to be taken by mouth) and contains 16 mg of betahistine dihydrochloride. The tablet can be divided into equal halves to create two doses of 8 mg each.

Betaserc 24 mg is a round, biconvex, scored, white tablet with beveled edges and the insignia S engraved on one side. On the other side, the tablet is scored and the number 289 is engraved on either side of the score line. This tablet is for oral administration (to be taken by mouth) and contains 24 mg of betahistine dihydrochloride.

The 24 mg tablet can be divided into equal halves. However, the purpose of the scoreline is only to facilitate breaking for ease of swallowing and does not divide the tablet into equal doses.

Excipients (non-medicinal ingredients): Microcrystalline cellulose, mannitol (E421), citric acid monohydrate, colloidal anhydrous silica and talc.

Indications

Ménière's Syndrome as defined by the following core symptoms:

- vertigo (dizziness with nausea/vomiting)
- hardness of hearing or hearing loss
- tinnitus (perception of sound in the ear in the absence of corresponding external sound (e.g. ringing))

Symptomatic treatment of vestibular vertigo (feeling of dizziness, often with nausea and/or vomiting, even when standing still).

Dosage and administration

Always take Betaserc exactly as your doctor has prescribed. If you have any questions, contact your doctor or pharmacist.

If you forget to take your tablet(s), do not take a double dose to compensate for it. If you require further information, please ask your doctor or pharmacist for advice.

Betaserc 8 and 16 mg:

The dosage for adults is 24–48 mg divided over the day.

8 mg tablets	16 mg tablets
1 – 2 tablets	½ – 1 tablet
3 times daily	3 times daily

Betaserc 24 mg:

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

Your doctor will adjust the dosage according to your response to the medication.

Be advised that improvement of symptoms may take up to two weeks and that best results are sometimes obtained only after a few months. There are indications that treatment from the onset of the disease prevents its progression and/or the loss of hearing in later phases of the disease.

Pediatric population:

Betaserc is not recommended for use in children under the age of 18 years due to insufficient data on safety and efficacy.

Geriatric population:

Although there are limited data from clinical studies in this patient group, extensive postmarketing experience suggests that no dose adjustment is necessary in this patient population.

Renal and/or hepatic impairment:

There are no specific clinical trials available in this patient groups, but according to postmarketing experience no dose adjustment appears to be necessary.

Contraindications

Do not take Betaserc if you are allergic (hypersensitive) to the active substance or to any of the excipients or if you suffer from an adrenal gland tumor known as a pheochromocytoma.

Warnings and special precautions for use

If you suffer from bronchial asthma or have a history of stomach (peptic) ulcer, your doctor will need to monitor you carefully while you are taking this medication.

Interactions with other medications

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines including medicines obtained without a prescription.

No interaction studies on living subjects (*in vivo*) have been performed. Based on laboratory (*in vitro*) data, no inhibition of Cytochrome P450 enzymes is expected in living subjects.

As betahistine is similar in structure to histamine, interaction of betahistine with antihistamines may affect the efficacy of one of these drugs. Tell your doctor if you are taking an antihistamine before taking Betaserc.

Pregnancy and lactation

Ask your doctor or pharmacist for advice before taking any medicine during pregnancy.

Pregnancy:

No enough information is available with regards to the use of Betaserc in pregnant women. Animal studies are also insufficient with respect to effects on pregnancy, embryonal/foetal development, giving birth and postnatal development. The potential risk for human foetuses and newborns in this regard is unknown. Do not take Betaserc during pregnancy unless it is deemed absolutely necessary by your doctor.

Lactation:

It is not known whether betahistine is excreted in human milk. There are no animal studies on the excretion of betahistine in milk. You should not take Betaserc if you are nursing. For further information, talk to your doctor regarding the importance of this medicine to you, the benefits of nursing and the potential risks to your child.

Effects on ability to drive and use machines

As shown in clinical studies, Betaserc is regarded to have no or negligible influence on the ability to drive and use machines.

Undesirable effects

Like all medicines, Betaserc may have side effects. If you notice any side effects not mentioned in this leaflet, or if any of the side effects get serious, please inform your doctor or pharmacist.

The following undesirable effects have been experienced with the below indicated frequencies in Betaserc-treated patients in placebo-controlled clinical trials: *common* (between 1 and 10 cases in 100 treated patients)

Gastrointestinal disorders

Common: nausea and indigestion (dyspepsia)

Nervous system disorders

Common: headache*

* The frequency of headache in placebo-treated patients (5.9% in a pool of 457 patients) was similar in comparison to Betaserc-treated patients (5.1% in a pool of 468 patients).

In addition to those events reported during clinical trials, the following undesirable effects have been reported spontaneously during postmarketing use and in scientific literature. A frequency cannot be estimated from the available data and is therefore classified as "not known".

Immune System disorders

Allergic (hypersensitivity) reactions, including a serious allergic reaction (anaphylaxis) which can cause difficulty breathing, face and neck swelling and dizziness.

Gastrointestinal disorders

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

Skin and subcutaneous tissue disorders

Allergic reactions of the skin or tissues under the skin, in particular a sudden onset of face, neck or limb swelling (angioneurotic oedema), hives (urticaria), rash and itchiness (pruritus).

Overdose

Symptoms of overdose

A few overdose cases have been reported. Some patients experienced mild to moderate symptoms such as nausea, sleepiness and abdominal pain with doses up to 640 mg. More serious complications including convulsions, and lung and heart complications were observed in cases of intentional overdose of Betaserc, especially when taken in combination with other overdosed drugs.

Treatment of overdose

No specific antidote is known. Treatment of overdose should include standard supportive measures.

Pharmacodynamics

Pharmacotherapeutic group: Anti-vertigo preparations.

The following is a detailed description of how the active ingredients of Betaserc work. For further explanations please consult your doctor.

The mechanism of action of betahistine is partly known.

In biochemical studies, betahistine was found to have weak H₁ receptor agonistic and potent H₃ antagonistic properties in both the central and autonomic nervous systems. Pharmacological testing in animals has shown that blood circulation in the striae vascularis of the inner ear improves, probably by means of a relaxation of the precapillary sphincters of the microcirculation of the inner ear.

Betahistine was also found to have a dose dependent inhibiting effect on spike generation of neurons in lateral and medial vestibular nuclei.

Betahistine accelerates the vestibular recovery after unilateral neurectomy, by promoting and facilitating central vestibular compensation; this effect, characterized by an up-regulation of histamine turnover and release, is mediated through H₃ Receptor antagonism.

Taken together these properties contribute to the beneficial therapeutic effects seen with regard to Ménière's disease and vestibular vertigo.

Betahistine increases histamine turnover and release by blocking presynaptic H₃-receptors and inducing H₃-receptor downregulation. This effect provides explanation for the efficacy of betahistine in the treatment of vertigo and vestibular diseases.

Pharmacokinetics

The following is a detailed description of how the active ingredients of Betaserc are metabolized by the body. For further explanations please consult your doctor.

Orally administered betahistine is readily and almost completely absorbed from all parts of the gastro-intestinal tract. After absorption, the drug is rapidly and almost completely metabolized into 2-PAA (which has no pharmacological activity). Plasma levels of betahistine are very low (i.e., below the detection limit of 100 pg/ml). All pharmacokinetic analyses are therefore based on 2-PAA measurements in plasma and urine.

The plasma concentration of 2-PAA reaches its maximum 1 hour after intake. The half-life is approximately 3.5 hours. 2-PAA is readily excreted in the urine. In the dose range of 8 to 48 mg, about 85% of the original dose is excreted in the urine. Renal or fecal excretion of betahistine itself is of minor importance. Recovery rates are constant over the oral dose range of 8 – 48 mg indicating that the pharmacokinetics of betahistine are linear, and suggesting that the involved metabolic pathway is not saturated. Under fed conditions C_{max} is lower compared to fasted conditions. However, total absorption of betahistine is similar under both conditions, indicating that food intake only slows down the absorption of betahistine.

Incompatibilities

Not applicable.

Shelf life and storage conditions

3 years, do not store above 30°C.

Store in the original package in order to protect from light.

Do not use the medicine after the expiry date stated on carton.

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

Pack sizes

Betaserc tablets are supplied in packages containing 10, 20, 30, 50, 60, 90, 100, 120, 500 or 1000 tablets (8 mg), 10, 14, 15, 20, 28, 30, 40, 50, 56, 60, 100, 200, 300, 400 or 500 tablets (16 mg) or 10, 20, 30, 40, 50, 60 or 100 tablets (24 mg) per pack (not all pack sizes may be marketed).

The blisters (bubble packs) are made of PVC/PVDC and aluminum lidding foil.

Further information

Any unused product or waste material should be disposed of in accordance with local requirements.

The information in this leaflet is limited. For further information, please contact your doctor or pharmacist.

Date of information

February 2010

Manufactured by:

Abbott Healthcare SAS

01400 Châtillon-sur-Chalaronne, France

for

ABBOTT HEALTHCARE PRODUCTS B.V., THE NETHERLANDS

THIS MEDICATION

is a product which affects your health and its use contrary to instructions is dangerous to you.

Strictly follow the doctor's prescription, the method of use and the instructions of the pharmacist who sold you the medication.

– The doctor and the pharmacist are the experts in medicines, their benefits and risks.

– Do not interrupt the period of treatment prescribed without talking to your doctor first.

– Do not repeat the same prescription without first consulting your doctor.

– Keep all medications out of reach of children.

Council of Arab Health Ministers,

Union of Arab Pharmacists.