BETASERC® OD

Betahistine dihydrochloride

Extended Release Film-Coated Tablet 48 mg

1. NAME OF THE MEDICINAL PRODUCT

Betaserc® OD Extended Release Film-Coated Tablet 48mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Betaserc® OD extended release film-coated tablet 48mg contains betahistine dihydrochloride corresponding to 31.26 mg betahistine.

For a full list of excipients see section list of excipients.

3 PHARMACEUTICAL FORM

Round biconvex tablet, yellow, coated and smooth on both sides.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

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

- vertigo (with nausea/vomiting)
- hearing loss (hardness of hearing)
- tinnitus

4.2 Posology and Method of Administration

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

48mg tablets
1 tablet Once Daily

Method of administration:

Should be swallowed whole with water.

Due to the properties of the extended release film-coated tablets, the tablet may not dissolve completely and the remainder of the tablet shell may appear in the stool.

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.

Paediatric population:

Betaserc®OD is not recommended for use in children below 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 post marketing experience suggests that no dose adjustment is necessary in this patient population.

Renal impairment:

There are no specific clinical trials available in this patient group, but according to post-marketing experience no dose adjustment appears to be necessary.

Hepatic impairment:

There are no specific clinical trials available in this patient group, but according to post-marketing experience no dose adjustment appears to be necessary.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients.

Phaeochromocytoma.

4.4 Special Warnings and Precautions for Use

Patients with bronchial asthma and history of peptic ulcer need to be carefully monitored during the therapy.

4.5 Interaction with Other Medicinal Products and Other Forms of Interaction

No *in vivo* interaction studies have been performed. Based on *in vitro* data no *in vivo* inhibition on Cytochrome P450 enzymes is expected.

In vitro data indicate an inhibition of betahistine metabolism by drugs that inhibit monoamino-oxidase (MAO) including MAO subtype B (e.g. selegiline). Caution is recommended when using betahistine and MAO inhibitors (including MAO-B selective) concomitantly.

As betahistine is an analogue of histamine, interaction of betahistine with antihistamines may in theory affect the efficacy of one of these drugs.

4.6 Fertility, Pregnancy and Lactation

Pregnancy:

There are no adequate data from the use of betahistine in pregnant women.

Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity

(see section 5.3). Betahistine should not be used during pregnancy unless clearly necessary.

Lactation:

It is not known whether betahistine is excreted in human milk. Betahistine is excreted in rat milk. Effects seen post-partum in animal studies were limited to very high doses (see section 5.3). The importance of the drug to the mother should be weighed against the benefits of nursing and the potential risks for the child.

Fertility

Animal studies did not show effects on fertility in rats.

4.7 Effects on Ability to Drive and Use Machines

Betahistine is indicated for Meniere's syndrome defined by the triad of core symptoms vertigo, hearing loss, tinnitus. Both diseases can negatively affect the ability to drive and use machines.

In clinical studies specifically designed to investigate the ability to drive and use machines betahistine had no or negligible effects.

4.8 Undesirable Effects

The following undesirable effects have been experienced with the below indicated frequencies in betahistine-treated patients in placebo-controlled clinical trials [very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000)].

Gastrointestinal disorders

Common: nausea and dyspepsia

Nervous system disorders

Common: headache

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

Immune System disorders

Hypersensitivity reactions, e.g. anaphylaxis

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

Cutaneous and subcutaneous hypersensitivity reactions, in particular angioneurotic oedema, urticaria, rash, and pruritus.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system email: pv.indonesia@abbott.com and/or via:

Pusat Farmakovigilans/MESO Nasional
Direktorat Pengawasan Keamanan, Mutu, dan Ekspor Impor Obat, Narkotika, Psikotropika, Prekursor, dan Zat Adiktif
Badan Pengawas Obat dan Makanan (BPOM) RI
Jl. Percetakan Negara No. 23, Jakarta Pusat, 10560, Indonesia
Email : pv-center@pom.go.id
Situs web: https://e-meso.pom.go.id

4.9 Overdose

A few overdose cases have been reported. Some patients experienced mild to moderate symptoms with doses up to 640 mg (e.g. nausea, somnolence, abdominal pain).

More serious complications (e.g. convulsion, pulmonary or cardiac complications) were observed in cases of intentional overdose of betahistine especially in combination with other overdosed drugs. Treatment of overdose should include standard supportive measures.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: Anti-vertigo preparations. ATC-Code: N07CA01

The mechanism of action of betahistine is only partly understood. There are several plausible hypotheses that are supported by animal studies and human data:

- Betahistine affects the histaminergic system:
  Betahistine acts both as a partial histamine H1-receptor agonist and histamine H3-receptor antagonist also in neuronal tissue, and has negligible H2-receptor activity. Betahistine increases histamine turnover and release by blocking presynaptic H3-receptors and inducing H3-receptor downregulation.

- Betahistine may increase blood flow to the cochlear region as well as to the whole brain:
  Pharmacological testing in animals has shown that the 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 shown to increase cerebral blood flow in humans.

- Betahistine facilitates vestibular compensation:
  Betahistine accelerates the vestibular recovery after unilateral neurectomy in animals, by promoting and facilitating central vestibular compensation; this effect characterized by an up-regulation of histamine turnover and release, is mediated via the H3 Receptor antagonism. In human subjects, recovery time after vestibular neurectomy was also reduced when treated with betahistine.

- Betahistine alters neuronal firing in the vestibular nuclei:
  Betahistine was also found to have a dose dependent inhibiting effect on spike generation of neurons in lateral and medial vestibular nuclei.

The pharmacodynamic properties as demonstrated in animals may contribute to the therapeutic benefit of betahistine in the vestibular system.

The efficacy of betahistine was shown in studies in patients with vestibular vertigo and with Ménière's disease as was demonstrated by improvements in severity and frequency of vertigo attacks.

5.2 Pharmacokinetic Properties

Absorption:

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-pyridylacetic acid. Plasma levels of betahistine are very low. Pharmacokinetic analyses are therefore based on 2-PAA measurements in plasma and urine.

Under fed conditions Cmax 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.

Distribution:

The percentage of betahistine that is bound by blood plasma proteins is less than 5 %.

Biotransformation:

After absorption, betahistine is rapidly and almost completely metabolized into 2-PAA (which has no pharmacological activity).

After oral administration of betahistine the plasma (and urinary) concentration of 2-PAA reaches its maximum 1 hour after intake and declines with a half-life of about 3.5 hours.

Excretion:

2-PAA is readily excreted in the urine. In the dose range between 8 and 48 mg, about 85% of the original dose is recovered in the urine. Renal or fecal excretion of betahistine itself is of minor importance.

Linearity:

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.

5.3 Preclinical Safety Data

Chronic toxicity

Adverse effects in the nervous system were seen in dogs and baboons after intravenous doses at and above 120 mg/kg.

Studies on the chronic oral toxicity of betahistine dihydrochloride were performed in rats over a period of 18 months and in dogs over 6 months. Doses of 500 mg/kg in rats and 25 mg/kg in dogs were tolerated without changes in the clinical chemical and hematological parameters. There were no histological findings related to treatment at these dosages. After increasing the dose to 300 mg/kg, the dogs showed vomiting. In an investigational study with betahistine in rats over 6 months at 39 mg/kg and above hyperemia in some tissues was reported in the literature. Data presented in the publication are limited. Therefore, the impact of this finding in this study is not clear.

Mutagenic and carcinogenic potential

Betahistine does not have mutagenic potential.

Special carcinogenicity studies were not performed with betahistine dihydrochloride. However, in the 18 months chronic toxicity studies in rats there was no indication of any tumors, neoplasms or hyperplasia in the histopathological examination. Therefore, betahistine dihydrochloride up to a dose of 500 mg/kg did not show any evidence for carcinogenic potential in this limited 18 months study.

Reproduction toxicity

Betahistine has no effects on fertility in male and female rats and is not teratogenic in rats and rabbits up to and including 1000 mg/kg for rats and 75 mg/kg in rabbits. In a pre- and postnatal development study in rats, lower pup weight, smaller litter size and lower viability in F1 pups and increased post implantation loss in F1 generation were seen at maternally toxic doses of 1000 mg. Lower average force for startle response test was observed in F1 pups of 300 and 1000 mg/kg dose groups. At 100 mg/kg, no effects on pre- and postnatal development were noted. The relevance of changes noticed at higher doses to humans is unknown.

6 PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Microcrystalline cellulose
Mannitol

Citric acid monohydrate
Co-processed polyvinyl acetate and povidone polymer
Talc
Opadry 03F180011 White
Opadry II 85F220031 Yellow

6.2 Incompatibilities

Not applicable

6.3 Shelf Life

Please refer to carton for expiry date.

6.4 Special Precautions for Storage

Store at or below 30°C.

6.5 Nature and Contents of Container

Betaserc® OD Extended Release Film-Coated Tablets 48mg are supplied in packs of 30 tablets. The tablets are packaged in OPA/ALU/PVC-Aluminum blisters (Alu-Alu Blisters).

6.6 Special Precautions for Disposal and Other Handling

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

Betaserc® OD 48 mg Extended release film coated tablet :
Box of 2 blisters @ 15 Extended release film coated tablet.
Reg No : DKIxxxxxxxxxxx

OBAT KERAS
HARUS DENGAN RESEP DOKTER

Manufactured by :
Abbott Laboratories de México, S.A. de C.V.
Calzada de Tlalpan No.3092, Col. Ex Hacienda Coapa, C.P. 04980
Coyoacán, Mexico City

Imported by :
PT Abbott Indonesia
Jl. Raya Jakarta-Bogor Km. 37, Depok – Indonesia

L008/07/23
Last revision : 07 Januari 2026

INFORMASI UNTUK PASIEN

Betaserc(R)OD
Betahistine dihidroklorida
Tablet Salut Selaput Selaput Pelepasan Lambat 48 mg

Bacalah seluruh brosur dengan seksama sebelum Anda mulai menggunakan obat ini karena brosur ini mengandung informasi penting.

- Simpan brosur ini. Anda mungkin ingin membacanya lagi nanti.
- Jika Anda memiliki pertanyaan lebih lanjut, silakan tanyakan kepada dokter atau apoteker Anda.
- Obat ini telah diresepkan hanya untuk Anda. Jangan diberikan kepada siapa pun. Hal tersebut dapat membahayakan orang lain, meskipun mereka mempunyai keluhan yang sama dengan Anda.
- Jika Anda mendapati adanya efek samping, silakan hubungi dokter atau apoteker Anda. Hal ini juga berlaku untuk efek samping yang tidak tercantum dalam brosur ini. Lihat bagian 4.

Apa yang ada di brosur ini

1. Apa itu Betaserc(R)OD dan kegunaannya

Apa itu Betaserc(R)OD

Betaserc(R)OD mengandung Betahistine, yang merupakan obat analog histamine.

Apa kegunaan Betaserc(R)OD

Betaserc(R)OD digunakan untuk mengobati penyakit berikut
Penyakit Meniere dengan gejalanya antara lain

- Vertigo dan mual atau muntah
- Bunyi pada telinga (tinnitus)
- Kesulitan mendengar

Bagaimana Betaserc(R)OD Bekerja

Betaserc(R)OD meningkatkan sirkulasi darah di telinga bagian dalam, yang mengurangi tekanan di area tersebut.

2. Apa yang perlu Anda ketahui sebelum menggunakan Betaserc(R)OD

Jangan menggunakan Betaserc(R)OD

- Jika Anda alergi terhadap Betahistine atau bahan lain dari obat ini (tercantum di bagian 6);
- Jika dokter Anda memberitahukan bahwa Anda memiliki tumor yang tumbuh dikelenjar adrenal, yang terletak dibagian atas ginjal (Phaeochromocytoma)

Jangan menggunakan obat ini jika salah satu hal di atas berlaku untuk Anda. Jika Anda tidak yakin, bicarakan dengan dokter atau apoteker Anda sebelum menggunakan obat ini.

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Peringatan dan pencegahan
Konsultasikan dengan dokter atau apoteker Anda sebelum menggunakan Betaserc(R)OD:

- Jika Anda memiliki ulkus peptic (sakit pada lambung)
- Jika Anda memiliki asma bronkial

Jika salah satu hal di atas berlaku untuk Anda atau Anda tidak yakin, tanyakan dokter atau apoteker Anda sebelum menggunakan Betaserc(R)OD. Dokter Anda mungkin akan memantau kondisi Anda lebih ketat daripada biasanya selama pengobatan dengan Betaserc(R)OD.

Anak-anak
Betaserc(R)OD tidak direkomendasikan untuk anak-anak dibawah umur 18 tahun.

Obat lain dan Betaserc(R)OD
Beritahu dokter atau apoteker Anda jika Anda sedang menggunakan, baru saja menggunakan, atau mungkin menggunakan obat lain, termasuk obat yang didapatkan tanpa resep dokter, atau obat herbal/tradisional.

Beri tahu dokter atau apoteker Anda khususnya jika Anda menggunakan obat-obatan berikut:

- Antihistamine (contoh: cetirizine, chlorpeniramine, dan lainnya) – obat-obatan ini (secara teori) mungkin dapat menurunkan efektifitas dari Betaserc(R)OD. Betaserc(R)OD juga dapat menurunkan efektifitas dari antihistamine.
- Monoamine-oxidase inhibitors (MAOIs) (contoh: isocarboxazid, dan lainnya) – obat-obatan ini digunakan untuk mengobati depresi dan penyakit Parkinson. Hal ini dapat meningkatkan paparan terhadap Betaserc(R)OD

Jika salah satu hal di atas berlaku untuk Anda atau Anda tidak yakin, bicarakan dengan dokter atau apoteker Anda sebelum menggunakan Betaserc(R)OD.

Betaserc(R)OD dengan Makanan dan Minuman
Betaserc(R)OD dapat dikonsumsi bersama makanan atau saat perut kosong. Namun, obat ini dapat menyebabkan gangguan lambung ringan (lihat bagian 4). Mengonsumsi Betahistine bersama makanan dapat membantu mengurangi masalah lambung.

Kehamilan dan menyusui
Tidak diketahui apakah Betaserc(R)OD mempengaruhi janin.

- Berhenti mengonsumsi Betaserc(R)OD dan beritahu dokter Anda jika Anda hamil atau menduga Anda hamil.
- Jangan mengonsumsi Betaserc(R)OD selama hamil, kecuali dirasa perlu menurut dokter Anda.

Tidak diketahui apakah Betaserc(R)OD diekskresikan dalam ASI.

- Jangan menyusui selama pengobatan dengan Betaserc(R)OD kecuali dokter Anda memberitahu bahwa Anda dapat melakukannya.

Mengemudi dan menggunakan mesin
Betaserc(R)OD mungkin memengaruhi kemampuan mengemudi atau kemampuan menggunakan alat atau mesin. Namun, perlu diperhatikan bahwa kondisi yang Anda alami saat mengonsumsi Betaserc(R)OD (penyakit Ménière) dapat menyebabkan pusing atau mual, sehingga mengganggu kemampuan Anda untuk mengemudikan kendaraan bermotor atau melakukan tugas yang memerlukan konsentrasi penuh. Merupakan tanggung jawab Anda untuk menilai apakah Anda mampu melakukan tugas-tugas ini. Bicaralah dengan dokter atau apoteker Anda jika Anda tidak yakin.

3. Bagaimana cara menggunakan Betaserc(R)OD

Selalu gunakan obat ini tepat seperti yang diinstruksikan oleh dokter atau apoteker Anda. Tanyakan kepada dokter atau apoteker Anda jika Anda tidak yakin.

- Dokter Anda akan menentukan jumah yang sesuai untuk Anda tergantung pada kondisi kesehatan Anda
- Teruskan minum obat. Mungkin perlu waktu sebelum obat tersebut tampak memberikan efek apa pun.

Cara pemberian

- Telan tablet dengan air.
- Anda dapat dikonsumsi obat ini bersama makanan atau saat perut kosong. Namun, obat ini dapat menyebabkan gangguan lambung ringan (lihat bagian 4). Mengonsumsi Betahistine bersama makanan dapat membantu mengurangi masalah lambung.

Dosis
Dosis yang dianjurkan adalah satu tablet per hari.

Jika Anda menggunakan Betaserc(R)OD lebih banyak dari yang seharusnya
Menggunakan Betaserc(R)OD dalam dosis yang terlalu besar akan menyebabkan mual, mengantuk atau tidur berlebihanter (somnolence), atau sakit perut. Jika Anda mengonsumsi obat dalam dosis yang terlalu besar atau, misalnya, anak Anda tidak sengaja mengonsumsi obat tersebut, selalu hubungi dokter Anda untuk menilai risiko dan menerima petunjuk tambahan.

Jika Anda lupa mengonsumsi Betaserc(R)OD

- Jika Anda lupa meminum satu dosis, minumlah dosis berikutnya pada waktu yang seharusnya.
- Jangan meminum dosis ganda untuk mengganti dosis yang terlewat.

Jika Anda berhenti menggunakan Betaserc(R)OD
Jangan berhenti menggunakan Betaserc(R)OD kecuali Anda sudah berdiskusi terlebih dahulu dengan dokter Anda, meskipun jika kondisi Anda sudah mengalami kemajuan.

Jika Anda memiliki pertanyaan lebih lanjut mengenai penggunaan obat ini, tanyakan kepada dokter atau apoteker Anda.

4. Kemungkinan efek samping

Seperti semua obat-obatan, obat ini dapat menyebabkan efek samping, meskipun tidak semua orang akan mengalaminya. Obat ini dapat menyebabkan efek samping berikut:

<u>Gangguan gastrointestinal</u>
Umum: mual dan dispepsia

<u>Gangguan sistem saraf</u>
Umum: sakit kepala
Selain kejadian yang dilaporkan selama uji klinis, efek samping berikut telah dilaporkan secara spontan selama penggunaan pasca pemasaran dan dalam literatur ilmiah. Frekuensi tidak dapat diperkirakan dari data yang tersedia dan oleh karena itu diklasifikasikan sebagai "tidak diketahui".

<u>Gangguan Sistem Kekebalan Tubuh</u>
Reaksi hipersensitivitas, misalnya anafilaksis

<u>Gangguan gastrointestinal</u>
Gangguan lambung ringan (misalnya muntah, nyeri gastrointestinal, perut kembung, dan terasa penuh. Kondisi ini biasanya dapat diatasi dengan mengonsumsi dosis saat makan atau dengan menurunkan dosis.

<u>Gangguan kulit dan jaringan subkutan</u>
Reaksi hipersensitivitas kulit dan subkutan, khususnya edema angioneurotik, urtikaria, ruam, dan pruritus.

Jika Anda mengalami efek samping, konsultasikan dengan dokter atau apoteker Anda. Ini termasuk efek samping yang mungkin tidak tercantum dalam brosur ini.

Pelaporan atas reaksi yang membahayakan
Jika Anda mengalami efek samping apa pun, beritahukan dokter atau apoteker Anda. Hal ini juga berlaku untuk efek samping yang tidak tercantum dalam brosur ini. Anda juga dapat melaporkan efek samping langsung ke pv.indonesia@abbott.com

Dengan melaporkan efek samping, Anda dapat membantu memberikan informasi lebih lanjut mengenai keamanan obat ini.

5. Cara Penyimpanan Betaserc(R)OD

Jauhkan obat ini dari jangkauan anak-anak.
Jangan simpan di atas suhu 30 °C.
Jangan gunakan obat ini setelah tanggal kedaluwarsa yang tertera pada karton dan kemasan blister. Tanggal kedaluwarsa mengacu pada hari terakhir bulan tersebut.

Jangan membuang obat apa pun melalui air limbah atau limbah rumah tangga. Tanyakan kepada apoteker Anda cara membuang obat yang tidak lagi Anda gunakan. Langkah-langkah ini akan membantu melindungi lingkungan.

6. Isi kemasan dan informasi lebih lanjut

Apa kandungan Betaserc(R)OD

- Kandungan aktifnya adalah Betahistine dihidroklorida. Satu tablet mengandung 48 mg Betahistine dihidroklorida.
- Bahan tambahan lainnya adalaha mikrokristalin selulosa, mannitol, asam sitrat monohidrat, Polimer polivinil asetat dan povidon yang diproses bersama, Talk, Opadry 03F180011 putih, dan Opadry II 85F220031 Kuning.

Seperti apa Betaserc(R)OD dan isi kemasannya
Betaserc(R)OD adalah tablet bikonveks bulat, kuning, berselaput dan halus di kedua sisi.

Betaserc(R)OD tersedia dalam kemasan *blister* berisi 30 tablet salut selaput pelepasan lambat.

Nomor Izin Edar : DKIxxxxxxxxxxx

OBAT KERAS
HARUS DENGAN RESEP DOKTER

Diproduksi oleh :
Abbott Laboratories de México, S.A. de C.V.
Calzada de Tlalpan No.3092, Col. Ex Hacienda Coapa, C.P. 04980
Coyoacán, Mexico City

Pendaftar :
PT. Abbott Indonesia
Jl. Raya Jakarta-Bogor, Km. 37
Depok, Indonesia

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