

Betahistine Core Safety Profile

4.2 Posology and method of administration

Pediatric population:

Betaserc not recommended for use in children below 18 years due to insufficient data on safety and efficacy.

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.

Oral Solution:

This medicinal product contains 5 vol% alcohol (ethanol). Considering the highest individual dose (3 ml = 120 mg), this would be equivalent to 3 ml beer or 1.5 ml wine per dose.

Harmful for those suffering from alcoholism. To be taken into account in pregnant or breast-feeding woman, children and high-risk groups such as patients with liver disease, or epilepsy.

May cause allergic reactions (possibly delayed).

Accidental inhalation of betahistine solution may, in theory, give rise to bronchospasms and decrease of blood pressure.

4.5 Interactions 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 P 450 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 Pregnancy and lactation

Pregnancy:

There are no adequate data from the use of betahistine in pregnant women. Animal studies are insufficient with respect to effects on pregnancy, embryonal/foetal development, parturition and postnatal development. The potential risk for humans is unknown. Betahistine should not be used during pregnancy unless clearly necessary.

Lactation:

It is not known whether betahistine is excreted in human milk. There are no animal studies on the excretion of betahistine in milk. The importance of the drug to the mother should be weighed against the benefits of nursing and the potential risks for the child.

4.7 Effect on ability to drive and to use machines

Betahistine is indicated for Morbus Meniere and symptomatic vertigo. 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 ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$); uncommon ($\geq 1/1,000$ to $< 1/100$); rare ($\geq 1/10,000$ 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.

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.