

VIRASERC

Tablets

Composition

Each tablet contains Betahistine hydrochloride 16 mg

Action

Chemically, betahistine has a close resemblance to histamine.

The mechanism of action of betahistine is unknown. 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.

In pharmacological studies, betahistine found to have weak H₁ receptor agonistic and considerable H₃ antagonistic properties in the CNS and autonomic nervous system. Betahistine also found to have a dose dependent inhibiting effect on spike generation of neurons in lateral and medial vestibular nuclei. The importance of this observation in the action against Meniere's syndrome or vestibular vertigo, however, remains unclear.

Pharmacokinetics

Orally administered doses of betahistine dihydrochloride are rapidly and completely absorbed from the gastrointestinal tract. The drug is rapidly metabolised to one major metabolite - 2-pyridylacetic acid - and excreted in the urine. Plasma half-life of 3.4 hours and a urinary half-life of 3.5 hours. Urinary excretion was about 90% complete within 24 hours of administration.

Indications

- Meniere's disease.
- Meniere-Like syndromes characterized by attacks of vertigo, tinnitus and/or progressive hearing loss.
- Symptomatic treatment of peripheral vertigo.

Contraindications

- During pregnancy and lactation
- Children less than 12 years
- Patients suffering from phaeochromocytoma
- Patients with active peptic ulcer or a history of this condition
- Patients with hypersensitivity to any component of the product

Warnings

Pregnancy

Category C

Administration to pregnant women is not recommended

Adverse Reactions

Gastrointestinal disturbances, including dyspepsia headache and skin rashes have been reported.

Precautions

Betahistine should be given with care to patients with asthma, peptic ulcer or a history of peptic ulcer. It has been suggested that it should not be given concomitantly with antihistamines.

Drug Interactions

Although an antagonism between Betahistine and antihistamines could be expected on a theoretical basis, no such interactions have been reported.

Diagnostic Interference

Betahistine does not produce false-positive reactions in standard diagnostic urine tests.

Dosage and Administration

Adults (including the elderly)

The usual initial dose is 8-16 mg 3 times daily, taken preferably with meals. Maintenance doses ranging from 24-48 mg daily have been recommended.

Although improvement can usually be observed within a few days, it is sometimes very gradual and only clearly noticeable after several weeks of treatment. Therefore, continued treatment is recommended, as optimal results are usually obtained after a few months.

Viraserc is well tolerated in long-term treatment. There is some evidence that treatment from the onset of the disease can prevent the progression of the syndrome and/or the hearing loss on the later stages.

Children

There are no dosage recommendations for children.

Over Dosage

There is no specific antidote for over dosage with Betahistine. Gastric lavage and symptomatic treatment recommended.

Presentation

Viraserc 16 mg

Box of 30 tablets