

TORHISGO 8/16

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for TORHISGO 8/16 [Betahistine dihydrochloride 8mg and 16 mg I.P]

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: 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: In biochemical studies, betahistine showed weak H1 receptor agonist and strong H3 antagonistic properties in the central nervous system and autonomic nervous system. The H2 receptor activity appeared to be negligible (e.g. stimulation of gastric acid secretion). Betahistine increases the turnover and release of histamine most likely by blocking presynaptic H3 receptors and inducing the downregulation of H3 receptors. Betahistine may increase blood flow to the inner ear: It has been shown in pharmacological animal experiments that betahistine improves the flow in the stria vascularis of the inner ear, probably by relaxing the precapillary sphincters of the microcirculation in the inner ear. Betahistine facilitates vestibular compensation: Betahistine accelerates vestibular healing after unilateral neurectomy in animals by stimulating and facilitating vestibular compensation; this effect, characterized by increases in histamine turnover and release, is mediated via H3 receptor antagonism. The recovery period after vestibular neurectomy was also reduced by betahistine in humans. Betahistine alters the release of neuron action potentials in the vestibular nuclei: Betahistine also has a dose-dependent inhibitory effect on the release of action potentials of neurons in the lateral and medial vestibular nuclei. Ménière's syndrome is characterized by attacks of dizziness, tinnitus, headache, nausea. Over time, hearing loss can occur. Clinical studies show that betahistine can prevent an attack and reduce the severity of attacks.

INDICATIONS: Betahistine is indicated in the treatment of Menier's syndrome, characterized by unilateral or bilateral tinnitus, vertigo, sensorineural hearing loss.

DOSAGE AND ADMINISTRATION: Initial oral treatment is 8 to 16 mg three times daily, taken preferably with meals. Maintenance doses are generally in the range 24 - 48 mg daily. Daily dose should not exceed 48 mg. Dosage can be adjusted to suit individual patient needs. Sometimes improvement could be observed only after a couple of weeks of treatment.

CONTRAINDICATION: Hypersensitivity to the active substance or to any of the excipients. Phaeochromocytoma- As betahistine is a synthetic analogue of histamine it may induce the release of catecholamines from the tumor resulting in severe hypertension

WARNINGS & PRECAUTIONS: Caution is advised in the treatment of patients with peptic ulcer or a history of peptic ulceration, because of the occasional dyspepsia encountered in patients on betahistine.

Clinical intolerance to Betahistine may occur in bronchial asthma patients. These patients should therefore be monitored carefully during the treatment with betahistine. Caution is advised in patients with severe hypotension

DRUG INTERACTIONS: 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 a histamine analogue, interaction of betahistine with antihistamines may in theory affect the efficacy of one of these drugs

ADVERSE REACTIONS: Headache, dyspepsia, nausea, anaphylaxis, vomiting, gastrointestinal pain, abdominal distension, bloating, cutaneous and subcutaneous hypersensitivity reactions, angioneurotic oedema, urticarial, rash and pruritus.

MARKETED BY:

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(Additional information is available on request)