For the Medical Profession Only

Histotec

Film coated tablets

Composition:

Each Film coated tablets contains:

Betahistine dihydrochloride .... 8, 16 mg

Inactive ingredients: Lactose, avicel, plasidone XL, stearic acid, aerosil 200, polyvinyl pyrolidone (K90).

Therapeutic indications:

Vertigo, tinnitus and hearing loss associated with Ménière's syndrome.

Posology and Method of administration:

Adults (including the elderly): Initially 16 mg three times daily taken preferably with meals. Maintenance doses are generally in the range 24 - 48 mg daily.

Children: No dosage recommendations.

Contraindications:

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

Special warnings and precautions for use:

Caution is advised in the treatment of patients with a history of peptic ulcer. Clinical intolerance to **Histotec** in bronchial asthma patients has been shown in a relatively few patients. These patients need to be carefully monitored during the therapy.

Interaction with other medicinal products:

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

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

Pregnancy and lactation:

Pregnancy:

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

Betahistine should not be used during pregnancy unless clearly necessary.

Lactation:

It is not known whether betahistine is excreted in human milk. The importance of the drug to the mother should be weighed against the benefits of nursing and the potential risks for the child.

Effects on ability to drive and to use machines:

Betahistine is regarded to have no or negligible effects on the ability to drive and to use machines as no effects potentially influencing this ability were found to be related to betahistine in clinical studies.

Undesirable effects:

Gastrointestinal disorders:

Common: nausea and dyspepsia.

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) have been reported.

Gastrointestinal disorders:

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

Nervous System disorders:

Headache.

Skin and subcutaneous tissue disorders:

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

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.

Pharmacological properties:

Pharmacodynamic properties:

The active ingredient is a specific histamine agonist with virtually no H2-activity. It appears to act on the precapillary sphincter in the stria vascularis of the inner ear, thus reducing the pressure in the endolymphatic space.

Pharmacokinetic properties:

Betahistine is rapidly and completely absorbed after oral administration of the drug in tablets. It is excreted almost quantitatively in urine as 2-pyridylacetic acid within 24 hours after administration. No unchanged betahistine has been detected.

Storage:

Store in a dry place at a temperature not exceeding 30°C. Store in the original package.

Package:

Histotec 8 mg Film coated tablets: Carton box containing 3 Blisters (AL/PVC) of 10 Film coated tablets each + insert leaflet.

Histotec 16 mg Scored film coated tablets: Carton box containing 2 Blisters (AL/PVC) of 10 scored film coated tablets each + insert leaflet.

Revision date:

January 2013.

This is a Medicament.

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use, and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not interrupt the period of treatment prescribed by yourself.
- Do not repeat the same prescription without consulting your doctor.
- Keep medicines out of the reach of children.

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