Actimed

Betahistine Hydrochloride

16 mg Film-Coated Tablet
ANTI-VERTIGO

℞

PRODUCT DESCRIPTION:
Betahistine Hydrochloride 16 mg is an off-white to grayish white film coated tablet; round, biconvex, bisected on one side and plain on the other side.

FORMULATION:
Each film-coated tablet contains:
Betahistine Hydrochloride, USP . . . . . 16 mg

PHARMACODYNAMICS:
The mechanism of action of betahistine hydrochloride is not known. Pharmacological testing in animals has shown that the blood circulation in the striae vascularis of the inner ear improved, due to relaxation of the precapillary sphincter of the microcirculation of the inner ear. In the pharmacological studies, betahistine hydrochloride was found to have weak H1 receptor agonist and considerable H3 antagonist properties in the CNS and autonomic nervous system. Betahistine hydrochloride was 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 of vestibular vertigo, however, remains unclear.

Betahistine hydrochloride is completely absorbed after oral administration.

Only one metabolite, 2-pyridylacetic acid which is excreted in urine is known.

PHARMACOKINETICS:
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-PAA (which has no pharmacological activity). Plasma levels of betahistine are very low (i.e., below the detection limit of 100 pg/mL). All pharmacokinetic analyses are therefore based on 2-PAA measurement in plasma and urine.

The plasma concentration of 2-PAA reaches a maximum 1 hour after intake. The half-life is approximately 3.5 hours. 2-PAA is readily excreted in the urine. In the dose range of 8 to 48 mg, about 85% of the original dose is excreted in the urine. Renal of fecal excretion of betahistine itself is of minor importance. 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. Cmax is lower under fed condition than in fasted condition. However, total absorption of betahistine is similar under both conditions, indicating that food intake only slows down the absorption of betahistine.

INDICATIONS:
Indicated in Meniere's Disease, Meniere – like syndrome (with symptoms of vertigo, tinnitus, and sensorineural deafness) and vertigo of peripheral origin.

DOSAGE AND ADMINISTRATION:
The dosage for adult is 24-48mg given in 2 or 3 divided doses over the day.
For 16 mg tablet: ½ - 1 tablet 3 times a day preferably with food.
Administration to children is not recommended.
Or as prescribed by the physician.

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.

PRECAUTIONS:
Betahistine should not be given to patients with pheochromocytoma. It should be given with care to patients with asthma, peptic ulcer disease, or with a history of peptic ulcer.

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

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/fetal 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 risk to the child.

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 metabolism by drugs that inhibit monoamino-oxidase (MAO) including MAO subtype B (e.g. selegeline). Caution is recommended when using betahistine and MAO inhibitors (including MAO-B selective) concomitantly.
As betahistine is an analogue of histamine, the interaction of betahistine with antihistamines may in theory affect the efficacy of one of these drugs.

ADVERSE DRUG REACTION:
Gastrointestinal disturbances, headache, skin rashes and pruritus.

OVERDOSE AND TREATMENT:
A few overdose cases have been reported. In most cases no overdose symptoms were reported. Some patients experienced mild to moderate symptoms at doses above 200 mg. At a dose of 728 mg a convulsion was reported. In all cases recovery was complete. Treatment of overdose should include standard supportive measures.

CAUTION:
Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.

ADR REPORTING STATEMENT:
For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph.
Seek medical attention immediately at the first sign of any adverse drug reaction.

STORAGE CONDITION:
Store at temperatures not exceeding 30°C.

KEEP OUT OF REACH OF CHILDREN.

AVAILABILITY:
Alu/Clear PVDC Blister Pack x 10's (Box of 100's)

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MANUFACTURED BY:
LLOYD LABORATORIES, INC.
No. 10 Lloyd Ave. First Bulacan Industrial City,
City of Malolos, Bulacan

MANUFACTURED FOR:
INNOGEN PHARMACEUTICALS, INC.
124-126 Dr. Lazcano St., Brgy. Sacred
Heart, Quezon City, Metro Manila

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