SUMMARY OF PRODUCT CHARACTERISTICS

BESTEDY 24

Betahistine Dihydrochloride Tablets BP 24 mg

R_x Only

NAME OF DRUG PRODUCT: Betahistine Dihydrochloride Tablets BP 24 mg.

(TRADE) NAME OF PRODUCT : BESTEDY 24

STRENGTH : 24 mg.

PHARMACEUTICAL DOSAGE FORM : Tablet.

QUALITATIVE AND QUANTITATIVE COMPOSITIONS:

Betahistine Dihydrochloride Tablets BP 24 mg:

Each un-coated tablet contains Betahistine Dihydrochloride Ph.Eur. 24 mg.

PHARMACEUTICAL FORM:

Betahistine Dihydrochloride Tablets BP 24 mg:

White to off-white round uncoated tablets debossed with 'X' and a break line on one side and '89'on the other side.

The tablet can be divided into two equal halves

CLINICAL PARTICULARS:

Therapeutic indications

Meniere 's syndrome as defined by the following triad of core symptoms:

- Vertigo (with nausea/vomiting)
- Hearing loss (hardness of hearing)
- Tinnitus (ringing in the ears)

Symptomatic treatment of vestibular vertigo

Posology and method of administration

The dosage for adults is 48mg divided over the day.

24 mg tablets

1 tablet

2 times/day

Method of administration:

BESTEDY 24 Betahistine Dihydrochloride Tablets: Should be swallowed with water.

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.

Paediatric population:

BESTEDY 24 Betahistine Dihydrochloride Tablets is not recommended for use in Children under the age of 18 years due to insufficient data on safety and efficacy.

Geriatric population:

Although there are limited data from clinical studies in this patient group, extensive post marketing experience suggests that no dose adjustment is necessary in this Patient population.

Renal impairment:

There are no specific clinical trials available in this patient group, but according to post-marketing experience no dose adjustment appears to be necessary.

Hepatic impairment:

There are no specific clinical trials available in this patient group, but according to Post-marketing experience no dose adjustment appears to be necessary.

Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients. Betahistine is contraindicated in patients with phaeochromocytoma. As betahistine is a synthetic analogue of histamine it may induce the release of catecholamines from the tumor resulting in severe hypertension.

Special warnings and precautions for use

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.

Patients with bronchial asthma should be monitored carefully during the treatment with betahistine.

Caution is advised in prescribing betahistine to patients with either urticaria, rashes or allergic rhinitis, because of the possibility of aggravating these Symptoms.

Caution is advised in patients with severe hypotension.

Interaction with other medicaments

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 an analogue of histamine, interaction of betahistine with antihistamines may in theory affect the efficacy of one of these drugs.

Pregnancy and lactation

Pregnancy:

There is a very limited amount of data from the use of betahistine in pregnant women. Animal studies, though insufficient do not indicate direct or indirect harmful effects with respect to reproductive. The potential risk for humans is unknown. As a precautionary measure, it is preferable to avoid the use of Betahistine during pregnancy.

Lactation:

There is insufficient information on the excretion of betahistine in human milk. There are no animal studies on the excretion of betahistine in milk. Betahistine should not be used during breastfeeding.

Effects on ability to drive and use machines

Betahistine is indicated for vertigo, tinnitus and hearing loss associated with Meniere's syndrome which 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.

Undesirable effects

The undesirable effects have been experienced with the below indicated frequencies in betahistine-treated patients: very common; common; uncommon; rare; very rare and not known.

Gastrointestinal disorders

Common: nausea and dyspepsia

Nervous system disorders:

Common: headache

Immune system disorders:

Not known: hypersensitivity reactions, e.g. anaphylaxis.

Gastrointestinal disorders

Not known: 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

Not known: cutaneous and subcutaneous hypersensitivity reactions, in particular angioneurotic oedema, urticarial, rash, and pruritus.

Over dosage

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). Other symptoms of betahistine overdose are vomiting, dyspepsia, ataxia and seizures. More serious complications (convulsion, pulmonary or cardiac complications) were observed in cases of intentional overdose of betahistine especially in combination with other overdosed drugs. No specific antidote. Gastric lavage and symptomatic treatment are recommended within one hour after intake.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Pharmacotherapeutic group: 2.7 Central Nervous System. Antiemetic and antivertigo

ATC code: N07C A01

The mechanism of action of betahistine is only partly understood.

A/s: 210 x 300 mm ■ Black

AUROBINDO Packaging Development		Product Name	Component	Item Code	Date & Time
		BESTEDY Tablets	Leaflet	P1535054	11.08.2023 & 04.00 pm
		Country	Version No.	Reason Of Issue	Reviewed / Approved by
		Malaysia_U3	00	Submission	
Team Leader	Kiran	Dimensions (mm)	Colours: 01		
Initiator	Shirisha	A/s: 210 x 300 mm	35054		
Artist	Sree Designers	Pharma Code: 35054			
Additional Information:					

Betahistine affects the histaminergic system

Betahistine acts both as a partial histamine H1-receptor agonist and histamine H3-receptor antagonist also in neuronal tissue, and has negligible H2-receptor activity.

Betahistine increases histamine turnover and release by blocking presynaptic H3-receptors and inducing H3-receptor downregulation.

Betahistine may increase blood flow to the cochlear region as well as to the whole brain:

The blood circulation in the striae vascularis of the inner ear may improve, probably by means of a relaxation of the precapillary sphincters of the microcirculation of the inner ear.

Betahistine may increase cerebral blood flow in humans.

Betahistine facilitates vestibular compensation:

Betahistine may accelerate the vestibular recovery after unilateral neurectomy, by promoting and facilitating central vestibular compensation; this effect, characterized by an up-regulation of histamine turnover and release, is mediated through H3 Receptor antagonism.

Recovery after vestibular neurectomy may also be reduced when treated with Betahistine.

Betahistine alters neuronal firing in the vestibular nuclei:

Betahistine may have a dose dependent inhibiting effect on spike generation of neurons in lateral and medial vestibular nuclei.

The betahistine in patients with vestibular vertigo and with Meniere's disease may cause improvements in severity and frequency of vertigo attacks.

Pharmacokinetic properties

Absorption

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-pyridylacetic acid. Plasma level of betahistine are very low. Pharmacokinetics analyses are therefore based on 2-PAA measurements in plasma and urine.

Under fed conditions C_{max} is lower compared to fasted conditions. However, total absorption of betahistine is similar under both conditions, indicating that food intake only slows down the absorption of betahistine.

Distribution

The percentage of betahistine that is bound by blood plasma proteins in less than 5%.

Biotransformation

After absorption, betahistine is rapidly and almost completely metabolized into 2-PAA (which has no pharmacological activity). After oral administration of betahistine the plasma (and urinary) concentration of 2-PAA reaches its maximum 1 hour after intake and declines with a half-life of about 3.5 hours.

Excretion

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 or fecal excretion of betahistine itself is of minor importance.

Linearity

Recovery rates are constant over the oral dose range of 8-48 indicating that the pharmacokinetics of betahistine are linear, and suggesting that the involved metabolic pathway is not saturated.

PHARMACEUTICAL PARTICULARS

List of excipients

Cellulose microcrystalline (Avicel PH 101), Mannitol, Povidone, Crospovidone, Citric acid, anhydrous, Cellulose microcrystalline (Avicel PH 112), Silica colloidal anhydrous, Talc and Stearic acid.

Incompatibilities

Not applicable.

Shelf life

Please refer outer package for expiry date.

Special precautions for storage

Do not store above 30 ^{0}C.

Protect from light and moisture.

Nature and contents of container

10x10's Blister Pack

Manufactured by:

AUROBINDO

Aurobindo Pharma Limited

Unit III Survey No. 313 314, Bachupally Village,
Bachupally Mandal, Medchal Malkajgiri District,
Hyderabad, Telangana, 500090, India.

Product Registration holder in Malaysia:
UNIMED SDN BHD
No. 53, Jalan Tembaga, SD 5/2B,
Bandar Sri Damansara, 52200,
Kaula Lumpur, Malaysia.

Date of Revision

15th October 2025

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