133.35 mm

203.2 mm

Betanex

8mg, 16mg and 24mg Tablets

(Betahistine Dihydrochloride)

بیٹانیکس

۸ ملی گرام

۱۶ ملی گرام اور

۲۴ ملی گرام ٹیبلیٹس

(بیٹاہسٹین ڈائی ہائیڈروکلورائیڈ)

Composition:
Each tablet contains:
Betahistine Dihydrochloride B.P. .....8mg.
Each tablet contains:
Betahistine Dihydrochloride B.P. .....16mg.
Each tablet contains:
Betahistine Dihydrochloride B.P. .....24mg.
(Product complies with Nexus Specifications)

Description:
The active ingredient of Betanex is betahistine dihydrochloride. Betahitine is a synthetic and orally active analogue of histamine. The major application of Betanex is in the treatment of Menieres disease and Meniere like syndrome characterized by severe attacks of vertigo, tinnitus and progressive loss of hearing frequently accompanied by nausea and vomiting.

Dosage and administration
Always take Betanex exactly as your doctor has prescribed. If you have any questions, you should check with your doctor or pharmacist.
If you forget to take your tablet(s), do no take a double dose to compensate for it. If you require further information, please ask your doctor or pharmacist for advice. The dosage for adults is 24-48 mg divided over the day.

8 mg tablets	16 mg tablets	24 mg tablets
1-2 tablets 3 times per day	1/2 -1 tablet 3 times per day	1 tablet 2 times per day

Your doctor will adjust the dosage according to your response to the medication. Improvement of symptoms may take up to two weeks and the best results are sometimes obtained only after a few months. There are indications that treatment from the onset of the disease prevents its progression and/or the loss of hearing in later phases of the disease.

Pediatric population:
Betanex is not recommended for use in children under the age of 18 years due to insufficient data on safety and efficacy.

Indications
Meniere's Syndrome as defined by the following core symptoms:
- vertigo (with nausea/vomiting)
- hearing loss (hardness of hearing)
- tinnitus (ringing in the ears)

Symptomatic treatment of vestibular vertigo.

Read this entire leaflet carefully before you start taking this medicine.
Keep this leaflet. You may need to read it again. If you have further questions, please ask your doctor or pharmacist. This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

Contraindications
Do not take Betanex if you are hypersensitive to the active substance or to any of the excipients.

Warnings and special precautions for use
If you suffer from a phaeochromocytoma or bronchial asthma, your doctor will need to monitor you carefully while you are taking this medication. Furthermore, please inform your doctor or pharmacist if you have a history of peptic ulcer before taking this medication.

Interactions with other medications
No in vivo interaction studies have been performed. Based on in vitro data, no in vivo inhibition on Cytochrome P450 enzymes is expected.
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines including medicines obtained without a prescription.

Pregnancy and lactation
Ask your doctor or pharmacist for advice before taking any medicine during pregnancy.
Pregnancy:
There is no adequate data for the use of betahistine in pregnant women. Animal studies are issufficient with respect to effects on pregancy, embryonal/foetal development. parturition (giving birth) and postnatal development. The potential risk for humans in this regard is unknown. Betahistine should not be used during preganacy unless is it deemed necessary by your docotor.
Lactation:
It is not know whether betahistine is excreated in human milk. There are no animal studies on the excretion of betahistine in milk . It is recommended not to take any medication while nursing. However if your are nursing , talk to your docotor regarding the importance of this medicine to you, the benefits of nursing and the potential risks to your child.

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

Important information about the ingredients
This product contains mannitol, which may have a mild laxative effect.

Undesirable effects
Like all medicines, Betanex may have side effects. If you notice any side effects not mentioned in this leaflet, or if any of the side effects get serious, please inform your doctor or pharmacist.

Undesirable Effects by System Organ Class:
Immune System disorders
Hypersensitivity (allergic) reactions (such as anaphylaxis) have been reported.
Gastrointestinal disorders
In some cases mild gastric complaints have been observed. These can normally be dealt with by taking the dose during meals or by lowering the dose.
Skin and subcutaneous tissue disorders
In very rare cases cutaneous (skin) hypersensitivity reactions have been reported, in particular angioneurotic oedema (sudden onset of face, neck or limb swelling), urticaria (hives),rash and pruritus (itchiness).

Overdose
Symptoms of overdose
A few overdose cases have been reported. Some patients experienced mild to moderate symptoms such as nausea, somnolence (sleepiness) and abdominal pain with doses up to 640mg.
More serious complications including convulsions, and pulmonary and cardiac complications were observed in cases of intentional overdose of Betanex, especially when taken in combination with other overdosed drugs.
Treatment of overdose
No specific antidote is known. Treatment of overdose should include standard supportive measures.

Pharmacodynamics
Pharmacotherapeutic group: Anti-vertigo preparations. The mechanism of action of betahistine is partly known. In biochemical studies, betahistine was found to have weak H_1 receptor agonistic and potent H_3 antagonistic properties in both the central and autonomic nervous systems. 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.
Betahistine was also found to have a dose dependent inhibiting effect on spike generation of neurons in lateral and medial vestibular nuclei.
Betahistne accelerates 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 H_3 Receptor antagonism.
Taken together these properties contribute to the beneficial therapeutic effects seen with regard to Meniere's disease and vestibular vertigo.
Betahistine increases histamine turnover and release by blocking presynaptic H_3 receptors and inducing H_3 receptor downregulation. This effect provides explanation for the efficacy of betahistine in the treatment of vertigo and vestibular diseases.

Pharmacokinetics
Orally administered betahistine is readily and almost completely absorbed from all parts of the gastrointestinal 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 measurements 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 or fecal excretion of betahistine itself is of minor importance. Recovery rates are constant over the oral dose range of 8 - 48mg indicating that the pharmacokinetics of betahistine are linear, and suggesting that the involved metabolic pathway is not saturated. Under fed conditions Cmax 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.

PRESENTATIONS
Shelf life and storage conditions
8 mg and 16 mg: 3 years, do not store above 30ºC.
24 mg: 3 years, do not store above 30°C.
Betanex 8mg tablets are available in
Alu-Alu blister pack of 30's
Betanex 16mg tablets are available in
Alu-Alu blister pack of 30's
Betanex 24mg tablets are available in
Alu-Alu blister pack of 30's
As directed by the physician.
Store at room temperature below (30°C).
Protect from sunlight & moisture.
Keep all medicines out of the reach of children.
To be sold on the prescription of a registered medical practitioner only.

عمومی خوراک اور طریقہ استعمال:
ڈاکٹر کی ہدایت کے مطابق استعمال کیجئے۔ دوا کو دھوپ اور نمی سے محفوظ کرے
۳۰ ڈگری سینٹی گریڈ سے کم کے درجہ حرارت پر رکھیں۔ تمام ادویات بچوں کی پہنچ سے دور رکھیں۔

Manufactured by:
NEXUS
Nexus Pharma (Pvt.) Ltd.
Plot No. 4/19 - 4/36, Sector 21,
Korangi Industrial Area, Karachi - Pakistan

Marketed by:
ORGANIC Pharmaceuticals