DIRECTIONS FOR USE

VESTIBO 8 mg
VESTIBO 16 mg
Tablets

COMPOSITION
Each tablet contains 8 mg Vestibo:
Active substance: betigastina dihydrochloride 8 mg.
Excipients: povidone, microcrystalline cellulose, lactose monohydrate, colloidal silicon dioxide, crospovidone, stearic acid.
Each tablet contains 16 mg Vestibo:
Active substance: betigastina dihydrochloride 16 mg.
Excipients: povidone, microcrystalline cellulose, lactose monohydrate, colloidal silicon dioxide, crospovidone, stearic acid.

DOSAGE FORM
Tablets

ACTION
The effect of betahistine through exposure to histamine H1- and H3-receptors (specific structures) are in the inner ear and some areas of the brain. It improves microcirculation and capillary permeability, normalizes blood pressure in the body balance of the endolymph, which is in the inner ear. The drug has no adverse effect on the functioning of the heart, in some cases can lead to a small reduction in blood pressure. Clinical manifestation of these effects is to reduce the frequency and intensity of vertigo, tinnitus reduction, improvement of hearing in the case of its reduction.

INDICATIONS
Vestibo used for the treatment of Meniere's disease, a manifestation of which are:
• vertigo (with nausea and / or vomiting);
• hearing loss (hearing);
• tinnitus.
Vestibo used for the treatment of manifestations t. Called. vestibular vertigo (dizziness caused by illness organ of balance).

NECESSARY INFORMATION BEFORE USE DRUG

CONTRAINDICATIONS
Do not take Vestibo at:
• hypersensitivity (allergy) to any component of the formulation;
• pheochromocytoma (tumor of the adrenal gland, which causes an increase in blood pressure) - the drug can lead to severe hypertensive crisis (excessive increase in blood pressure).

SPECIAL WARNINGS
Pay special attention when using Vestibo in the following cases:
- Patients with ulcer - because the risk of dyspepsia (heartburn, a burning sensation, nausea, gastric discomfort) during treatment;
- Patients with bronchial asthma, urticaria, rash and allergic rhinitis (there is an increased risk for patients with allergic diseases because of the likelihood of deterioration of allergy symptoms during treatment with betahistine);
- Patients with low blood pressure;

- Patients with histamine (cluster-periodic) and migraine headache because of the danger of provoking attacks during treatment with betahistine;
- Patients taking antihistamines (medicines to treat allergies).

Interactions with other medicinal products and other forms of interaction

Please inform your doctor or pharmacist that you are taking or have recently taken any other medicines, even if they are sold without prescription.

Vestibo should not be used concurrently with antihistamines (allergy) medications.

Alcohol, pyrimethamine (antimalarial drugs), salbutamol (antiasthmatic agents) enhance the effect Vestibo.

WARNINGS FOR some patient groups

Use during pregnancy and lactation

Before taking any medication, consult with your doctor or pharmacist.

These observations in animals indicate no harmful effects on the offspring. Vestibo safety during pregnancy in humans has not been proved and therefore his appointment pregnancy is not recommended.

Excreted in the breast milk, reaching concentrations similar to those in plasma. No data on the adverse effects on infants. In the period of lactation should be avoided use of the drug.

Effects on ability to drive and work with technology

Does not affect the performance of work requiring special attention, such as driving a car or operating machinery.

In rare cases can cause drowsiness and in such cases, patients should avoid work related to the need to improve concentration.

Application Vestibo and eating and drinking

Taken during edy.Net data to follow a special diet or taking certain limited food and beverages during treatment with this drug.

Information about excipients

Due to the presence of lactose in the composition as an auxiliary substance, the drug should be avoided in patients with intolerance to some sugars.

If your doctor said that you have intolerance to some sugars, consult with them before taking this drug.

Information on correct use

DOSAGE AND ADMINISTRATION

Always use Vestibo exactly in accordance with the instructions of your doctor. If you are in something not sure, check with your doctor.

Dosage selected individually, according to the response of the patient. Depending on the complaints, the doctor will determine the need to treat your disease dose.

Typical doses for adult

The daily dose is 24 - 48 mg, divided into two or three doses.

Tablets are taken with meals.

Children

This drug is not indicated for children and adolescents under 18 years of age.

Efficacy and safety in these groups has not been proven.

In some patients, improvement may occur after a 14-day course of treatment.

OVERDOSE

When you receive a dose exceeding the destination, consult a doctor immediately!

Symptoms of overdose include nausea, vomiting, dyspepsia (gastric distress), ataxia (loss of balance and coordination) and seizures.

In case of overdose you must delete the contents of the stomach, causing vomiting, by gavage and washing, and the use of suitable drugs for the treatment of the manifestations of overdose.

When symptoms of overdose, contact a doctor immediately!

If you miss a Vestibo

If you missed the one taking the drug, take it at the next regular admission.

ADVERSE REACTIONS

As with any drug, Vestibo can cause adverse reactions, even though they do not appear at all.

During treatment Vestibo possible adverse reactions from the various organs and systems with the following frequency: very frequent (≥1 / 10); frequent (≥1 / 100 to <1/10); not frequent (≥1 / 1,000 to <1/100); Rare (≥1 / 10,000 to <1/1000); very rare (<1/10000), with unknown frequency (in cash can not make an assessment of the data).

Disorders of the immune system

Very rare - skin rash and itching.

Disorders of the nervous system

With unknown frequency - headache and drowsiness.

Gastrointestinal disturbances

Rare - gastrointestinal upset, nausea, dyspepsia (heartburn, burning, nausea, stomach discomfort).

Cardiac disorders

Rare - heartbeat.

Respiratory, thoracic and mediastinal violation

Rare - aggravation of existing asthma symptoms.

Disorders of the skin and subcutaneous tissue

Rare - variables skin reactions with skin inflammation, itching and hives.

General disorders and effects at the injection site

Rare - sensation of heat.

If any of the side effects become serious, or if you have observed side effects not listed in this leaflet, please inform your doctor or pharmacist.

PACKING

Tablets 8 mg, 10 pieces in blister. 3 blisters with leaflet in carton box.

Tablets 16 mg, 10 pieces in blister. 3 blisters with leaflet in carton box.

STORAGE

At a temperature not exceeding 25 ° C.

Keep out of reach of children!

Medicines should not be disposed of via wastewater or household waste container. Ask your pharmacist how to destroy unneeded drugs. These measures will help to protect the environment.

EXPIRATION DATE

3 (three) years from date of manufacture.

Do not use after the expiry date shown on the packaging.

Expiry date corresponds to the last day of this month.

Do not use Vestibo if you notice change of pill.

Conditions of supply of pharmacies

By prescription.

MANUFACTURER

Balkanfarma-Dupnitsa AD
in collaboration with Catalent Germany Schorndorf GmbH
st. Samokov Highway 3, 2600 Dupnitsa, Bulgaria
tel .: +359/701 58196, Fax: 58555 +359/701