PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

Betahistine Teva® 16 mg
Tablets

The active ingredient and its quantity:
Each tablet contains: Betahistine dihydrochloride 16 mg

For the list of inactive ingredients, please see section 6.

Read this leaflet carefully in its entirety before using this medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.
This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar.
This medicine is not intended for children and adolescents below the age of 18 years.

1. WHAT IS THE MEDICINE INTENDED FOR?
- The medicine is intended to treat Meniere's syndrome, which is manifested by dizziness, ringing in the ears (tinnitus), and for the symptomatic treatment of peripheral vertigo.
- The medicine works by improving the blood flow in the inner ear, which reduces the build-up of pressure.

Therapeutic group:
Histamine analog.

2. BEFORE USING THE MEDICINE:

X Do not use the preparation if:
- If you are sensitive to the active ingredient or to any of the ingredients of the medicine (see details in section 6).
- If you suffer from high blood pressure as a result of an adrenal tumor (pheochromocytoma).

Special warnings regarding use of the medicine:
- If you are sensitive to any food or medicine, inform the doctor before taking this medicine.
- In asthma patients medical monitoring is required during the course of treatment with Betahistine.
- The preparation contains lactose and may cause an allergy in people sensitive to lactose.

! Before treatment with Betahistine Teva® 16 mg, tell the doctor if:
- If you are pregnant, planning to become pregnant or breastfeeding.
- If you are suffering, or have suffered in the past, from impaired function of: the respiratory system (e.g., asthma) or the digestive system (e.g., ulcer).

! If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.
It is especially important to inform the doctor or pharmacist if you are taking medicines from the following groups:
- Antihistamines – these medicines may lower the effect of Betahistine Teva®. Also, Betahistine Teva® may lower the effect of antihistamines.
- Monoamine oxidase inhibitors (MAOIs) – for treatment of depression or Parkinson's – these medicines may increase the effect of Betahistine Teva®.

! Use of the medicine and food:
Take the medicine with or without a meal.

! Use of the medicine and alcohol consumption:
Wines and alcoholic beverages can be consumed during the course of treatment with this medicine.

! Pregnancy and breastfeeding:
Do not take this medicine if you are pregnant, unless the doctor has decided that it is absolutely necessary. Consult the doctor.
Do not breastfeed while using this medicine, unless the doctor has instructed you otherwise. It is not known if the medicine passes into the breastmilk.

! Driving and use of machines:
Taking this medicine is not expected to impair the ability to drive or operate machinery. Despite this, remember that the ailments for which Betahistine is taken, may cause dizziness or nausea, which may affect the ability to drive and operate machinery.

! Important information about some of the ingredients of the medicine:
The medicine contains 140 mg lactose.

3. HOW SHOULD YOU USE THE MEDICINE?
Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are unsure.
Use this medicine at specified time intervals, as determined by the attending doctor.
It may take time until the effect of the tablets becomes apparent.

The dosage and the treatment regimen will be determined by the doctor only. The usual dosage is generally:
One tablet three times a day.
The doctor may lower the dosage to half a tablet three times a day.
Do not exceed the recommended dose.
This medicine is not intended for children and adolescents below the age of 18 years.
Do not chew; swallow the tablets with water.
The tablet can be halved at the score line.

Tests and follow-up
In asthma patients medical monitoring is required during the course of treatment with Betahistine.

If you accidentally took a higher dosage
If you took an overdose or if a child accidentally swallowed the medicine, immediately refer to a doctor or to a hospital emergency room and bring the package of the medicine with you. Do not induce vomiting without explicit instruction from a doctor!
Possible side effects of overdose – nausea, sleepiness or abdominal pains.

If you forgot to take this medicine at the scheduled time, do not take a double dose. Take the next dose at the regular time and consult a doctor.
Adhere to the treatment as recommended by the doctor.
Even if there is an improvement in your health, do not stop treatment with this medicine without consulting the doctor or pharmacist.
Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.
If you have further questions regarding use of this medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS:
As with any medicine, use of Betahistine Teva® 16 mg may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Discontinue use of this medicine and refer to a doctor immediately if:
If you suffer from allergic reactions, such as:
- Swelling of the face, lips, tongue or neck, which may cause difficulty breathing.
- A red skin rash, inflamed and itchy skin.

Additional side effects:
Occurring frequently (affect less than 1 in 10 patients): nausea, indigestion, headache.

Occur at an unknown frequency: itching, rash, mild gastrointestinal disorders, such as vomiting, abdominal pain and bloating. Taking this medicine with a meal can reduce the side effects associated with the digestive system.
If one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult the doctor.

5. HOW SHOULD THE MEDICINE BE STORED?
- **Avoid poisoning!** This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store in a dry place, below 25ºC. Store in the original package in order to protect from light.
- Do not discard medicines in the waste bin. Ask the pharmacist how to dispose of medicines no longer in use. These measures will help protect the environment.

6. FURTHER INFORMATION
- **In addition to the active ingredient, the medicine also contains:**

Lactose monohydrate, Microcrystalline cellulose, Crospovidone, Stearic acid, Colloidal silica anhydrous, Povidone K90.

- **What the medicine looks like and the contents of the package:**

Tablet form: a round, white to almost white tablet, with B16 appearing on one side and a score line on the other side.
The package contains 30 tablets.

- **License holder and address:** Abic Marketing Ltd., P.O.B. 8077, Nathanya.
- **Manufacturer and address:** Disphar International B.V., Hengelo, The Netherlands.
- **Registration number of the medicine in the National Drug Registry of the Ministry of Health:** 150.24.33758.00
- This leaflet was checked and approved by the Ministry of Health in July 2013.

TEVA