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 information on inactive and allergenic ingredients, see section 2 "Important information about some of the ingredients of the medicine" and section 6 "Further Information".

Read the leaflet carefully in its entirety before using the 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.

1. WHAT IS THE MEDICINE INTENDED FOR?

- To treat Meniere's syndrome.
- Symptomatic treatment of peripheral vertigo.

Therapeutic group: Antivertigo

The medicine contains betahistine, which is a histamine analog used to treat symptoms of Meniere's syndrome: dizziness (vertigo), ringing in the ears (tinnitus), hearing loss or difficulty hearing.
The medicine works by improving blood flow in the inner ear, which reduces the build-up of pressure.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:
- You are sensitive (allergic) to betahistine (the active ingredient) or to any of the additional ingredients contained in the medicine (see section 6).
- You suffer from an adrenal gland tumor (pheochromocytoma).

Special warnings regarding use of the medicine
Before treatment with Betahistine Teva 16 mg, consult the doctor if:
- You suffer from asthma
- You suffer from a stomach ulcer
- You are pregnant, think you are pregnant or are planning to become pregnant
- You are breastfeeding

If any of the conditions described above apply to you, the doctor will advise you whether it is safe for you to start taking Betahistine Teva.
The doctor may also want to monitor your asthma during the course of treatment with Betahistine Teva.

Drug interactions
If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular, inform the doctor or pharmacist before starting treatment if you are taking:
- 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 disease – these medicines may increase the effect of Betahistine Teva.

Children and adolescents
Betahistine Teva is not recommended for use in children under 18 years of age, because there are not enough data on the safety and efficacy of use.

Use of the medicine and food
Take the medicine with or after a meal.

Pregnancy and breastfeeding
Do not take Betahistine Teva when pregnant, unless the doctor has decided it is essential.
It is not known whether Betahistine Teva passes into breast milk. Do not breastfeed while using the medicine, unless otherwise instructed by the doctor.

Driving and use of machines
Betahistine Teva is not supposed to impair your ability to drive or use tools or machinery.
However, remember that the diseases for which you are taking this medicine (vertigo, tinnitus and hearing loss associated with Meniere's syndrome) can make you feel dizzy or nauseated, which may affect your ability to drive and operate machines.

Important information about some of the ingredients of the medicine
The preparation contains lactose and may cause allergy in people sensitive to lactose.
Each tablet contains 140 mg lactose.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions. The doctor will adjust the dosage according to your medical condition. The effect of Betahistine Teva may not be immediate.
Check with the doctor or pharmacist if you are uncertain regarding the dosage and treatment regimen.
The dosage and treatment regimen will be determined by the doctor only.
The usual dosage for adults is generally: One tablet (16 mg), three times a day.
If necessary, it is possible to start with a dosage of 8 mg (half a tablet), three times a day.
The daily dosage ranges from 24 to 48 mg and it is recommended to divide it into three equal doses throughout the day in order to ensure the level of the medicine in your body is constant. Try to take the tablets at the same time each day.

Do not exceed the recommended dose.

Method of administration
Swallow the medicine with water. It is recommended to take the medicine with food.
The tablet may be halved at the score line. There is no information regarding crushing and chewing.

If you accidentally took a higher dosage
If you took an overdose or if a child accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.
If you forgot to take this medicine at the required time, do not take a double dose. Take the next dose at the regular time and consult a doctor.
Adhere to the treatment regimen as instructed by the doctor. Even if there is an improvement in your health, do not stop treatment with the 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 the 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 the medicine and refer to a doctor immediately if the following side effects occur:
Allergic reactions , such as:
- Swelling of the face, lips, tongue or neck, which may cause difficulty breathing.
- A red skin rash or inflamed and itchy skin.

Common side effects (effects that occur in 1-10 users in 100):
Nausea, indigestion, headache.

Additional side effects:
Itching, rash, hives (an allergic reaction of blood vessels in the skin), mild gastrointestinal disorders, such as vomiting, abdominal pain and feeling bloated.
Taking the medicine with food will help reduce these effects.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Reporting side effects
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il

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 25°C. 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.

What the medicine looks like and the contents of the package:
Round, white to almost-white tablet, with B16 appearing on one side and a score line on the other.
The package contains 30 tablets.

License Holder and its Address:
Abic Marketing Ltd., P.O.B. 8077, Netanya

Manufacturer and its 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
This leaflet was revised in December 2020 according to MOH guidelines

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