

**PATIENT LEAFLET IN ACCORDANCE
WITH THE PHARMACISTS'
REGULATIONS (PREPARATIONS) – 1986**

The medicine is dispensed with a doctor's prescription only

Betistine 16 mg Tablets

Active ingredient:

Each tablet contains:

Betahistine dihydrochloride 16 mg.

For the list of the additional ingredients, see section 6. See also "Important information about some of the medicine's ingredients" in section 2.

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or the pharmacist.

This medicine has been prescribed for your treatment. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. What is the medicine intended for?

For treatment of Meniere's syndrome.

For symptomatic treatment of peripheral vertigo.

Therapeutic class:

antivertigo.

The medicine contains betahistine, which is a histamine analogue, used to treat symptoms of Meniere's syndrome, which include: dizziness (vertigo), ringing in the ears (tinnitus), hearing loss, difficulty hearing.

The medicine works by improving blood flow in the inner ear, which reduces pressure buildup.

2. Before using the medicine

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient (betahistine) or to any of the additional ingredients the medicine contains (for the list of additional ingredients, see section 6).
- You suffer from an adrenal gland tumor (pheochromocytoma).

Special warnings regarding the use of the medicine:

Before (and during) treatment with Betistine 16 mg, tell the doctor if:

- You suffer from asthma (the doctor may wish to monitor your asthma condition during the treatment).
 - You suffer or have suffered in the past from a stomach ulcer.
 - You are pregnant, think you are pregnant or are planning a pregnancy.
 - You are breastfeeding.
- If any of the conditions above apply to you, the doctor will advise you whether it is safe for you to use the medicine.

Children and adolescents

Betistine 16 mg is not recommended for use in children and adolescents under the age of 18, since there is not enough data on the safety and efficacy of the medicine in this age group.

Drug interactions:

If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist. In particular, inform the doctor or pharmacist before starting and during treatment with **Betistine 16 mg** if you are taking:

- Medicines from the monoamine oxidase inhibitors (MAOIs) group for treatment of

depression or Parkinson's disease. These medicines may increase the effect of **Betistine 16 mg**.

- Antihistamine medicines: these medicines may lower the effect of **Betistine 16 mg**. Also, **Betistine 16 mg** may lower the effect of antihistamine medicines.

Use of the medicine and food

It is advisable to take **Betistine 16 mg** with or after food.

Pregnancy and breastfeeding

- Do not take **Betistine 16 mg** when pregnant, unless your doctor has decided it is essential.
- It is not known whether the medicine passes into breast milk. Do not breastfeed during the treatment with **Betistine 16 mg**, unless your doctor has instructed you otherwise.

Driving and use of machinery

Betistine 16 mg should not impair your ability to drive or operate tools or machinery.

However, vertigo, tinnitus and hearing loss associated with Meniere's syndrome can cause dizziness and nausea, and may adversely affect your ability to drive and operate machinery.

Important information about some of the medicine's ingredients

The tablet contains lactose. If you have been told by the doctor that you have an intolerance to certain sugars, consult the doctor before taking the medicine.

3. How to use the medicine?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and manner of treatment with the medicine. The dosage and treatment regimen will be determined only by the doctor.

The doctor will adjust the dosage according to your medical condition. The effect of the medicine may not be immediate.

The generally accepted dosage for adults is: 16 mg three times a day.

If necessary, it is possible to start with a dosage of 8 mg three times a day. If a dosage of 8 mg is required, the tablet can be halved according to the score line debossed on the tablet.

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 that the level of the medicine in your body is constant.

Try to take the tablets at regular times every day.

Do not exceed the recommended dose.

Method of administration: swallow the medicine with water. It is advisable to take the medicine with food.

Crushing/halving/chewing: there is no information about crushing or chewing the tablets. The tablets can be halved according to the score line debossed on the tablet.

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 a hospital emergency room and bring the medicine package with you.

If you forgot to take the medicine:

If you forgot to take this medicine at the required time, do not take a double dose to compensate for the forgotten dose. Take the next dose at the usual time and consult a doctor.

Adhere to the treatment as recommended by the doctor. Even if there is an improvement in your state of health, do not stop treatment with the medicine without consulting the doctor.

Do not take medicines in the dark! Check the label and the dose every time you take a medicine. Wear glasses if you need them. If you have further questions regarding the use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, using **Betistine 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 and refer to a doctor immediately if the following side effects occur:

Allergic reactions such as:

- Red skin rash or inflamed and irritated skin.
- Swelling in the face, lips, tongue or neck. These effects may cause breathing difficulties.

Common side effects (effects that occur in 1-10 users out of 100):

Nausea, digestive difficulties, headaches.

Additional side effects:

- Irritation, rash, hives (an allergic reaction of blood vessels in the skin).
- Mild gastrointestinal disorders, such as vomiting, abdominal pain and a feeling of abdominal bloating. 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.

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which leads to the online form for reporting side effects, or by clicking on the link: <https://sideeffects.health.gov.il/>

5. How to store the medicine?

Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.

Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.

Storage conditions: store in the original package, below 25°C.

Do not discard medicines via wastewater or household waste. Ask the pharmacist how to dispose of medicines no longer in use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, the medicine also contains:

Lactose monohydrate, microcrystalline cellulose, crospovidone, stearic acid, silica colloidal anhydrous, povidone K90.

What the medicine looks like and what the package contains:

Round, white tablets, one side is debossed with a score line and the other side is debossed with 'B16'.

The tablets are packed in a blister pack, 30 tablets in a box.

Manufacturer and registration holder: Rafa Laboratories Ltd., P.O. Box 405, Jerusalem 9100301, Israel.

Medicine registration number in the national medicines registry of the Ministry of Health: 120-76-30126-11

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