

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

The medicine is dispensed with a doctor's prescription only

Agiserc 16 Tablets

Composition:

Each tablet contains: betahistine dihydrochloride 16 mg.

Inactive and allergenic ingredients in the preparation – see section 6 “Additional information”.

Read this entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, refer to the doctor or 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 the treatment of Meniere's syndrome.

For the symptomatic treatment of peripheral vertigo.

Therapeutic group: Antivertigo preparations.

Agiserc 16 contains betahistine which is a histamine analogue used to treat symptoms of Meniere's syndrome:

dizziness (vertigo), ringing in the ears (tinnitus), hearing loss or difficulty hearing.

Agiserc 16 works by improving blood flow in the inner ear, which lowers the build up of pressure.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are hypersensitive (allergic) to betahistine (the active ingredient) or to any of the additional ingredients contained in the medicine (see section 6 “Additional information”).
- You suffer from an adrenal gland tumor (pheochromocytoma).

Special warnings regarding use of the medicine

Before treatment with Agiserc 16, 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 above applies to you, the doctor will advise you whether it is safe for you to start taking Agiserc 16.

The doctor may also want to monitor your asthma during the course of treatment with Agiserc 16.

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 with Agiserc 16 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 Agiserc 16.
- Antihistamines which may lower the effect of Agiserc 16. Also, Agiserc 16 may lower the effect of antihistamines.

Children and adolescents:

Agiserc 16 is not recommended for treatment in children under the age of 18, because there is not enough data on the safety and efficacy.

Use of the medicine and food

Agiserc 16 can be taken with or after food.

Pregnancy and breastfeeding:

- Do not take Agiserc 16 when pregnant, unless your doctor has decided it is essential.
- It is not known whether Agiserc 16 passes into breast milk. Do not breastfeed if you are taking Agiserc 16, unless your doctor has instructed you otherwise.

Driving and use of machinery:

Agiserc 16 should not impair 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 vomit, and may affect your ability to drive and operate machines.

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 Agiserc 16 may not be immediate.

You should check with the doctor or pharmacist if you are not sure about the dosage and manner of treatment with the medicine.

The dosage and manner of treatment will be determined by the doctor only.

The usual dosage for adults is generally: 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, it is possible to use other medicines that are registered in Israel that contain betahistine dihydrochloride 16 mg in tablets which can be halved to receive 8 mg.

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.

Crushing/halving/chewing: In order to make swallowing easier, if necessary, it is possible to halve the tablet for immediate use. Swallow both halves one after the other immediately after halving. There is no information about crushing and chewing.

If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you.

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

Adhere to the treatment 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.

Do not take medicines in the dark! Check the label and the dose each 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 pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Agiserc 16 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 the doctor immediately if the following side effects occur:

Allergic reactions such as:

- A red skin rash or inflamed itchy skin.
- Swelling of the face, lips, tongue or neck. These may cause breathing difficulties.

Common side effects (appear 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 gastric problems such as vomiting, abdominal pain and feeling of abdominal bloating.

Taking Agiserc 16 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 this leaflet, consult with the doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link “Reporting 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>

In addition, they can be reported to Padagis via the following link: www.padagis.co.il

5. HOW SHOULD THE MEDICINE BE STORED?

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 explicit instruction from the doctor.

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 cool place, below 25°C.

- Protect from light and moisture.

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: Microcrystalline cellulose, Mannitol, Citric acid monohydrate, Silica colloidal anhydrous.

- What the medicine looks like and the contents of the package: Tablets packaged in blister trays. Each package contains 30 tablets. The tablets are round, white and marked with a score line on one side and embossed on the other side with “Agiserc”.

- Manufacturer name and Registration holder: Padagis Israel Pharmaceuticals Ltd., 1 Rakefet St., Shoham.

- Drug registration number in the National Drug Registry of the Ministry of Health:

Agiserc 16 Tablets 056-8727365.

This leaflet was revised in September 2023 according to MOH guidelines.