

**Partial 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 ingredients in the medicine - 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?

The medicine is intended for the treatment of Meniere's syndrome, symptomatic treatment of peripheral vertigo.

**Therapeutic group:** Antivertigo preparations.

Agiserc 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. Agiserc 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).
- You suffer from an adrenal gland tumor (pheochromocytoma).

### Special warnings regarding use of the medicine

**Before treatment with Agiserc, 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.

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

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

### Children and adolescents

Agiserc 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 can be taken with or after food.

### Pregnancy and breastfeeding

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

### Driving and use of machinery

Agiserc 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 according to the doctor's instructions. The doctor will adjust the dosage according to your medical condition. The effect of Agiserc 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 which 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 accidentally taken a higher dosage

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

### If you forgot to take the medicine

If you forgot to take the 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.

Continue 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 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 the medicine with food will help reduce these effects.

**If a side effect appears 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 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 colored and marked with a score line on one side and "Agiserc" embossed on the other side.
- **Manufacturer and Registration holder:** Perrigo Israel Pharmaceuticals Ltd., P.O.B. 16, Yeruham.
- Revised in June 2020.
- Drug registration number in the National Drug Registry of the Ministry of Health: 5687.27365

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