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

The medicine is dispensed with a doctor's prescription only.

AGISTEN

Lozenges

Clotrimazole 10 mg

Inactive and allergenic ingredients in the preparation – see section 6 in the leaflet. **Read this 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 you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar. The medicine is not intended for children under the age of 3. You must use it in the correct manner. Consult the pharmacist if you need further information. Refer to the doctor if signs of the illness (symptoms) worsen or do not improve after 7 days.

1. WHAT IS THE MEDICINE INTENDED FOR?

For local treatment of Candida infections diagnosed in the oral cavity and pharynx. For prophylactic treatment to reduce the incidence of oropharyngeal candidiasis in patients immunocompromised by chemotherapy, radiotherapy, steroid therapy in leukemia, solid tumors and renal transplantation.

Therapeutic group: Anti-inflammatory for local oral treatment.

2. BEFORE USING THE MEDICINE

X Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient clotrimazole or to any of the additional ingredients contained in the medicine.

Special warnings regarding use of the medicine

- Agisten lozenges are not intended for the treatment of systemic fungal infection.
- Do not use this medicine for a prolonged period without consulting a doctor.
- The medicine may affect the results of liver function tests.

! Before treatment with Agisten lozenges, tell the doctor if

- you are sensitive to any food or medicine.
- you are pregnant or breastfeeding.

! If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

! Pregnancy and breastfeeding

If you are pregnant or breastfeeding, consult the doctor.

! Important information about some of the ingredients of the medicine

The preparation contains sugar! Each lozenge contains 888 mg Dextrose.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain.

The dosage and treatment regimen will be determined by the doctor only. The usual dosage is generally:

For treatment of an existing Candida infection: One lozenge five times a day for two weeks.

For prophylactic treatment in immunocompromised patients: One lozenge three times a day for the duration of chemotherapy or until steroids are reduced to a fixed daily dose.

Do not exceed the recommended dosage. The lozenge is intended for sucking - allow the lozenge to dissolve slowly in the mouth for about 15-30 minutes – do not swallow.

Tests and Follow-up

It is recommended to perform periodic liver function tests, particularly in patients with existing liver disease.

If you took an overdose, or if a child has 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. Adhere to the treatment regimen as recommended by the doctor. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting with the doctor.

- 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 a doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Agisten lozenges 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.

In addition to the desired effect of the medicine, side effects such as: nausea, vomiting, a sensation of discomfort in the mouth, pruritus, may occur during the use of this medicine.

Side effects that require special attention:

The medicine can affect the results of liver function tests (see special warnings in section 2). 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 from 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://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

In addition, you can report to Perrigo via the following address: www.perrigo-pharma.co.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by 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 below 25°C.
- Can be used for 4 weeks after first opening, but not later than the expiry date.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains: Dextrose, microcrystalline cellulose, povidone, magnesium stearate. The preparation contains sugar! Each lozenge contains 888 mg Dextrose.

- What does the medicine look like and what are the contents of the package: A bottle containing 70 white to off-white round flat lozenges, debossed with "PAD 0107" on one side.
- Registration holder: Perrigo Israel Agencies Ltd., 1 Rakefet St., Shoham, 6085000.
- Manufacturer: Paddock Laboratories, LLC (Perrigo Minnesota), Minneapolis, Minnesota, USA.
- This leaflet was checked and approved by the Ministry of Health in August 2017.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 15913.34540