

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

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

AGISPOR® SHAMPOO

Each bottle contains: Bifonazole 1% w/w

Inactive and allergenic ingredients in the preparation – see section 6 “Further information” and in section 2 “Important information about some of the ingredients of the medicine”.

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 to treat you. 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?

Pityriasis versicolor and seborrheic dermatitis of the scalp caused by pityrosporum.

Therapeutic group: A broad-spectrum antifungal from the imidazole class.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient or any of the other ingredients of the medicine.

Special warnings regarding use of the medicine

- Patients using warfarin should be monitored more closely
- **Before treatment with Agispor, tell the doctor if**
- you have had an allergic reaction to any antifungal preparation

Children and adolescents

Analysis of clinical data has found that use in infants and toddlers must be under medical supervision.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially inform the doctor or pharmacist if you are taking warfarin, which is used to prevent and to treat blood clots. **Pregnancy, breastfeeding and fertility**
Do not use the medicine during pregnancy or when breastfeeding without explicit instruction from the doctor.

There is no preclinical evidence of impaired male or female fertility.

Driving and using machinery

There is no limitation on driving or operating dangerous machinery while using the medicine.

Important information about some of the ingredients of the medicine
This medicine contains 33.8 grams sodium lauryl sulfate per 100 grams medicine, which may cause local skin reactions (such as stinging or burning sensation) or increase skin reactions caused by other products when applied on the same area.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by the doctor only. The recommended dosage is generally: three time a week.

At each treatment, shampoo the scalp twice. Shake the bottle well, apply a measured amount of shampoo, wash and lather the affected skin with Agispor Shampoo and wait 5 minutes before rinsing. Make sure that you shampoo the skin itself and not the hair.

Do not exceed the recommended dose.

The maximal duration of use is 4 weeks. If your condition does not improve, refer to a doctor again.

For external use only. Do not swallow. Shake before use. Avoid contact of the preparation with the eyes. Avoid sharing towels with other people due to risk of transmission of the fungal infection.

If you took a higher dosage, or if a child has accidentally swallowed the medicine, refer immediately to the doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

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

Adhere to the treatment regimen as recommended by the doctor.

Even if there is an improvement in your condition, 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 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 Agispor Shampoo 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.

As with use of other medicines, some people are allergic to the medicine. If you are allergic, the allergic reaction will occur shortly after using the preparation. If you suffer from an allergic reaction, stop use immediately and refer to a doctor or for medical care.

Allergic side effects include:

- rash • difficulty swallowing or breathing • swelling of the lips, face, throat or tongue • weakness, dizziness, faintness • nausea

After using the medicine, you may experience the following side effects:

- slight irritation or burning • redness • peeling

Additional possible side effects:

- burning, pain or itching sensation • rash, redness, dryness • soft or soggy appearance of the skin • swelling, blisters, urticaria

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 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 website (www.health.gov.il), which directs you to an online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>
In addition, they can be reported to Padagis through the following address: 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 sight and reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without explicit instructions 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. Storage conditions

- Store in a cool place below 25°C.

- Can be used for 6 months after first opening, but no later than the expiry date.

- Store in the original packaging.

6. FURTHER INFORMATION

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

Sodium lauryl sulfate, Sodium laureth sulfate, Ethyl alcohol, Cocamidopropylamine oxide, Cocamide diethanolamine, Lactic acid, Jessica MOD 1, Purified water

- What the medicine looks like and the contents of the package:

A plastic bottle containing 100 milliliters of Agispor Shampoo.

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

- This leaflet was revised in February 2025 in accordance with the Ministry of Health guidelines.

- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 126-23-26745

- Agispor is a registered trademark of Padagis Israel Pharmaceuticals Ltd.