

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

The medicine is dispensed without a doctor's prescription

Agispor Cream, Gel, Solution

Each Agispor tube of cream or gel or bottle of solution contains:

Bifonazole 1%

Inactive ingredients and allergens in the preparation - see section 6.

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.

Refer to the doctor if the symptoms worsen or if they do not improve within 7 days.

1. WHAT IS THE MEDICINE INTENDED FOR?

Broad spectrum antifungal medicine.

Therapeutic group: Imidazole antifungal.

2. BEFORE USING THE MEDICINE

Do not use the medicine:

- if you are sensitive (allergic) to the active ingredient or to any of the other ingredients in the medicine.
- for treatment of diaper rash. If your baby has a diaper rash, refer to a doctor for appropriate treatment.
- for treatment of inflammation of the nails and scalp.
- for treatment of vaginal inflammations.

Special warnings regarding use of the medicine

Before treatment with Agispor, inform the doctor if

- you have previously had an allergic reaction to any kind of antifungal agent.
- **Agispor Solution: Warning! Flammable, keep away from fire. Do not light a cigarette or be exposed to an open flame until the product has completely dried.**

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, inform the doctor or pharmacist. It is particularly important to inform the doctor or pharmacist if you are taking warfarin.

Pregnancy and breastfeeding

Do not use the medicine if you are pregnant or breastfeeding, except with the doctor's recommendation.

Use in children and infants

Use in infants and toddlers must be done under medical supervision.

Important information regarding some of the ingredients of the medicine

The medicine contains cetyl stearyl alcohol, which may cause local skin irritation (e.g., rash, itching or redness) (in the cream and gel only).

Concentration of the preservative agent: benzyl alcohol 1% (in the cream and gel only).

Do not allow the medicine to come into contact with the eyes. In case of contact, wash immediately with water.

3. HOW SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are uncertain.

The usual dosage is generally:

Use once a day, preferably in the evening at bedtime.

Gently massage into the skin.

Continue with the treatment for 2-3 weeks.

Cream: a small amount of cream is sufficient to treat an area the size of the palm of the hand.

Gel: a strip of gel half a centimetre long is sufficient to treat an area the size of the palm of the hand.

Solution: a few drops (about 3 drops) are sufficient to treat an area the size of the palm of the hand.

Do not exceed the recommended dose

For external use only. Do not put in the mouth or swallow.

If the medicine accidentally came into contact with the eyes or mouth, wash immediately with water and refer to the doctor.

If a child or anyone else 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.

If you forgot to apply the medicine at the designated time, apply it as soon as possible and continue treatment as usual.

How can you contribute to the success of the treatment?

- Although the affected area will itch, try to avoid scratching it. Scratching can damage the surface of the skin and cause the infection to spread further.
- Keep the affected areas clean.
- Humidity enhances fungal growth. Therefore, keep the affected area dry.
- Wash the affected area before each application of the medicine. Between treatments - antifungal powder can be used to dry the area.
- Always wash your hands after treating the infection to prevent it from spreading.
- Do not share towels, bath mats, etc. with other people, as you could spread the infection to them.

If the treatment is for the feet – take care to thoroughly wash and dry them, especially between the toes, but avoid excessive rubbing. It is recommended to wear cotton socks; avoid wearing socks made from wool or from synthetic materials. It is advisable to change them several times a day (in accordance with the amount of sweat).

- Thoroughly wash socks, nylon stockings and tights in hot water to remove any peeled skin or fungal spores.
- Change your shoes every day, if possible.
- In the appropriate seasons, it is recommended to wear sandals without socks.
- Do not take medicines in the dark! Check the label and dose each time you take a 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 Cream, Gel or Solution may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

As with all medicines, some people may be allergic to the medicine. If you are allergic, a reaction will occur immediately after you start use. If you experience an allergic reaction, stop use and seek medical assistance immediately. The signs of an allergic reaction may include:

- Rash.
- Swallowing or breathing problems.
- Swelling of the lips, face, throat or tongue.
- Weakness, dizziness or faintness.
- Nausea.

After applying the medicine, you might experience one of the following symptoms:

- Slight irritation or burning.
- Reddening of the skin.
- Peeling.

If the effects are intolerable, stop treatment and refer to the doctor as soon as possible.

The medicine may cause local skin irritation which is very similar to the symptoms of the infection. If any of the symptoms worsen, stop treatment and refer to the doctor as soon as possible.

These symptoms may include:

- Skin inflammation.
- Burning, pain or itching.
- Rash, redness, dryness.
- Soft- or soggy-looking skin.
- Swelling, edema, hives (red, raised and itchy lesions), eczema, blisters.

If any of the side effects worsen, or if you suffer from a side effect not mentioned in this leaflet, consult the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting side effects following drug treatment" found on the Ministry

of Health page (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=AdverEffectMedic@moh.gov.il>

In addition, 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 must be kept in a safe place out of the sight and reach 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) that appears on the package. The expiry date refers to the last day of that month.
- Store in a cool place below 25°C.
- For the cream and gel: after first opening can be used for 3 months.
- Store in the original package.

6. FURTHER INFORMATION

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

Agispor Cream:

Sorbitan monostearate, polysorbate 60, cetyl esters wax-NF, cetyl stearyl alcohol, 2-octyldodecanol, benzyl alcohol, purified water.

Agispor Gel:

Polyoxyethylene 30 cetyl stearyl alcohol, macrogol 7 glycerol cocoate, isopropyl isostearate, ethanol, lactic acid, benzyl alcohol, purified water. Concentration of the preservative: Benzyl alcohol 1%.

Agispor Solution:

Ethanol, isopropyl myristate.

What the medicine looks like and the contents of the package:
Agispor Cream: An aluminium tube, 15 grams.

Agispor Gel: An aluminium tube, 15 grams.

Agispor Solution: A brown glass vial with 15 ml. of solution.

Manufacturer and registration holder: Perrigo Israel Pharmaceuticals Ltd., P.O.B. 16, Yeruham.

This leaflet was checked and approved by the Ministry of Health in January 2016.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Agispor Cream: 036-82-25608

Agispor Gel: 036-81-25610

Agispor Solution: 036-83-25609

Do not discard medicines via household waste or wastewater. Ask the pharmacist how to discard medicines you no longer need. These measures will help to protect the environment.