

Agispor Onycho-set/Keratospor Ointment

Each tube contains:

Bifonazole 1%

Urea 40%

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.

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 THIS MEDICINE INTENDED FOR?

Antifungal preparation for the treatment of fungal infections of the fingernails and toenails and for nail stripping.

Therapeutic group

Bifonazole - imidazole antifungal.

Urea - an organic compound for treatment of dry skin.

2. BEFORE USING THE MEDICINE

Do not use the medicine:

if you are sensitive (allergic) to the active ingredients or to any of the other ingredients in the medicine.

Special warnings regarding use of the medicine

Before treatment with Agispor Onycho-set/Keratospor, inform the doctor if

- you have a known sensitivity to antifungals from the imidazole group such as: econazole, clotrimazole, miconazole.
- you are sensitive to any food or medicine.

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

If you are pregnant, consult a doctor. Use of this preparation is not recommended in the first trimester of pregnancy.

Do not use if you are breastfeeding.

Use in children and infants

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

Important information regarding some of the ingredients of the medicine

The medicine contains wool wax (=wool fat).

Avoid contact between the ointment and the eyes. In case of contact with the eyes, wash thoroughly with water.

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.

Do not exceed the recommended dose.

For external use only. Do not swallow.

Avoid contact with the eyes.

Directions for use:

Agispor Onycho-set: Read the enclosed treatment guide carefully and make sure to precisely follow the directions and instructions for the use of the ointment tube and other treatment kit accessories.

Keratospor: Soak the sole of the foot or the palm of the hand in a bowl of warm water. Then dry thoroughly. Place tube with its grooved end into the slit of the plastic screw. Slowly turn the screw handle until enough ointment to cover the length of the affected nail emerges. Place the strip of ointment on the nail. Do not rub! Bandage the digit with a water-resistant plaster. The plaster acts as a protective cover and should be left on the nail for 24 hours. After 24 hours remove the plaster from the digit and re-immers the palm or sole in a bowl of warm water. Dry thoroughly. Use a file to remove the softened, affected nail substance. Do this carefully. Apply the ointment again as described above. Replace the plaster every day.

It is not necessary to also cover the skin surrounding the nail. However, in case of irritation, apply a suitable product on the skin surrounding the nail before dressing.

After removing the nail, refer to a doctor to complete the treatment and to clean the remaining nail.

If a child or anyone else accidentally swallowed the medicine, immediately refer 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 do not apply a double dose. Apply the next dose at the scheduled time and consult a doctor.

Adhere to the treatment regimen recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor or pharmacist.

How can you contribute to the success of the treatment?

Humidity enhances fungal growth. Therefore, keep the affected area dry.

Wash the affected area before each application of the medicine. Between treatments with the ointment - antifungal powder can be used to dry the area.

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

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 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 Onycho-set/Keratospor 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.

- Skin effects, in the subcutaneous tissue and in the treated area: Contact dermatitis, allergic dermatitis, erythema, pruritus, rash, urticaria, blistering, skin exfoliation, eczema, dry skin, skin irritation, skin maceration, burning sensation, nail problems, nail discoloration, pain and/or edema in the treated area and limb pain.

These effects pass after discontinuation of treatment, but if the above effects persist and/or are bothersome, refer to the doctor.

In case of an allergic reaction to the provided plasters (see "Directions for use"), such as rash: consult the doctor.

If any of the side effects worsen, 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 safe place out of the sight and reach 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, not above 25°C.
- After first opening can be used for 3 months.
- Store in the original package.

6. FURTHER INFORMATION

- In addition to the active ingredients, the medicine also contains: Wool fat, beeswax white, paraffin white soft.
- What the medicine looks like and the contents of the package:
Agispor Onycho-set: One 10 gram aluminium tube containing yellowish ointment, plasters, filer and plastic screw.
- **Keratospor:** One 10 gram aluminium tube containing yellowish ointment and a plastic screw.
- 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 August 2014.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health:
Agispor Onycho-set: 123-58-26495
Keratospor: 105-78-26596