Patient Package Insert in Accordance with the Pharmacist's Regulations (Preparations) – 1986
This medicine can be sold without a physician's prescription

Agispor Gel
Agispor Solution

Active ingredient and its concentration:
Each tube of gel contains Bifonazole 1% w/w
Each bottle of solution contains Bifonazole 1% w/v

Inactive ingredients and allergens in the medicine – see section 2 "Important information about some of the ingredients of this medicine" and section 6 "Additional information" in this leaflet.

Read this entire leaflet carefully before using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, refer to the physician or pharmacist.
Use this product according to the instructions in the dosage section in this leaflet. Consult the pharmacist if you need additional information. Contact a physician if the symptoms of your illness get worse or if they do not improve within 7 days.

1. WHAT IS THE MEDICINE INTENDED FOR?

Broad spectrum antimycotic agent.

Therapeutic group: Antifungal of the imidazole group for local use.
Bifonazole, the active ingredient in Agispor, penetrates the infected skin layers and kills the fungus there. It also has an anti-inflammatory (antiphlogistic) effect.

2. BEFORE USING THE MEDICINE

Do not use the medicine:
- If you are hypersensitive (allergic) to the active ingredient bifonazole, to benzyl alcohol or to any of the other ingredients this medicine contains (see section 2 "Important information about some of the ingredients of this medicine" and section 6 "Additional information").
- Agispor Solution is not intended for treatment of the ear canal.

Special warnings regarding the use of the medicine
Before the treatment with Agispor inform the physician if:
- You have previously had an allergic reaction to any antifungal agent (for example, with the active ingredient econazole, clotrimazole, miconazole); you should use Agispor with caution.
- Do not allow Agispor to come into contact with the eyes. In case of contact wash immediately with water.
- **Agispor Gel** can be used to treat nail bed skin fungus only after prior (keratolytic) removal of the nail material infected with fungi.
- **<u>Agispor Solution</u>: Warning! Flammable substance, keep away from fire. Do not light a cigarette or be exposed to an open flame until the product has completely dried.**

Children and infants
Use in children and infants must be done under medical supervision.
Make sure the gel or solution does not enter the mouth of the child and/or infant.

Drug interactions
If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, inform the physician or pharmacist. Especially if you are taking:
Warfarin – limited information suggests that an interaction between topically administered bifonazole and warfarin may be possible, resulting in an increase in the blood clotting factor (INR value). Therefore, if bifonazole and warfarin are used together, appropriate monitoring is necessary.

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult a physician or pharmacist before using this medicine.
There are insufficient data on the use of bifonazole in pregnant women.
As Agispor is a medicine applied only to the skin and a systemic effect (effect on other organs) is therefore not anticipated, no risk is expected. Nevertheless, as a precautionary measure, Agispor should be used during pregnancy only after a risk/benefit assessment. The use of Agispor should be avoided in the first three months of pregnancy.
Breastfeeding should be interrupted during treatment with bifonazole.
There are no studies of the effect of bifonazole on human fertility.

Driving and using machinery
Agispor has no or a negligible effect on the ability to drive or operate machinery.

Important information about some of the ingredients of this medicine
<u>Agispor Gel contains</u>:
- 10 mg benzyl alcohol per 1 g gel. Benzyl alcohol may cause allergic reactions.
- Stearates – when using Agispor Gel together with latex products (e.g., condoms, diaphragms) the adjuvants (stearates) can reduce their functionality and thus decrease their reliability.

3. HOW TO USE THE MEDICINE

Check with the physician or pharmacist if you are not sure about the dosage and the treatment regimen of the product.
The usual recommended dosage is:
Use once a day, preferably in the evening before sleeping.
Spray or apply a thin layer on the infected area and gently massage into the skin.

<u>How to use</u>:
Before using Agispor, wash the infected areas of the skin to remove loose flakes of skin and residues from the previous treatment. After washing, dry well, especially areas that are difficult to reach, for example, between the toes.
<u>Gel</u>: an amount of gel approximately a half centimeter long is sufficient to treat an area the size of the palm of a hand.
<u>Solution</u>: a few drops (approximately 3 drops) are sufficient to treat an area the size of the palm of a hand.

<u>Duration of use</u>:
To achieve long-term healing, do not stop the treatment with Agispor even after the severe inflammation symptoms or discomfort have passed, but continue to the following treatment durations:
- Foot mycoses (between the toes and on the feet): 3 weeks.
- Mycoses on the rest of the body, hands and skin folds (palms, hairless skin areas, crotches): 2-3 weeks.
- Pityriasis versicolor, erythrasma: 2 weeks.
- Superficial candidiasis of the skin: 2-4 weeks.

Refer to the physician if the symptoms get worse or do not improve within 7 days.

Do not exceed the recommended dose.

For external use only.

Do not put in the mouth or swallow.

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

If you accidentally took a higher dosage, continue the treatment according to the recommended dosage. No negative effect is expected from a short-term overdose.
If a child or anyone else has accidentally swallowed the medicine, proceed immediately to a physician or a hospital emergency room and bring the medicine package with you.

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

If you stop using the medicine, remember it is important to use Agispor for a sufficient period of time (see section 3 "Duration of use") to complete the healing effects and avoid recurrence.

Refer to the physician or pharmacist if you are considering stopping the treatment earlier than recommended.

Do not take medicines in the dark! Check the label and dose <u>each time</u> you take a medicine. Wear glasses if you need them.

If you have further questions on the use of this medicine, consult the physician or pharmacist.

4. SIDE EFFECTS

As with any medicine, the use of Agispor 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.
The following side effects were identified during the use of Agispor. Because they were reported voluntarily from patient groups of unknown sizes, the frequency cannot be estimated from the available data.

Significant side effects or signs you should be aware of and must act on if you experience them: If you experience one of the side effects mentioned below, stop the use of Agispor and refer to the physician as soon as possible:
- pain in the treated area
- peripheral edema (in the treated area)
- dry skin
- skin irritation
- softening of the skin
- skin exfoliation
- redness
- burning
- itching
- rash
- eczema
- blisters
- hives (red, raised and itchy lesions)
- contact dermatitis
- allergic dermatitis

These side effects are temporary and subside after the end of the treatment.
Benzyl alcohol may cause allergic reactions.

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

<u>Reporting of side effects</u>:
Side effects can be reported to the Ministry of Health by clicking on the link "Reporting Side Effects from Drug Treatment" that can be found on the home page of the Ministry of Health website (<u>www.health.gov.il</u>) directing you to the online form of adverse events reporting or by clicking on the following link: <u>https://sideeffects.health.gov.il</u>
Additionally, side effects can be reported to the Padagis company via the following address: <u>Padagis.co.il</u>

5. HOW TO STORE THE MEDICINE

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the physician.
- 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.
- Can be used for 3 months after first opening, but not later than the expiry date.
- <u>Agispor Gel</u>: store in a cool place below 25°C.
- <u>Agispor Solution</u>: store below 25°C.
  Warning! Flammable substance, keep away from fire.

6. ADDITIONAL INFORMATION

In addition to the active ingredient the medicine also contains:
<u>Agispor Gel</u>:
Polyoxyethylene 30 cetyl stearyl alcohol, Macrogol 7 glycerol cocoate, Isopropyl isostearate, Ethanol, Lactic acid, Benzyl alcohol, Purified water
<u>Agispor Solution</u>:
Isopropyl myristate, Ethanol

- What does the medicine look like and the contents of the package:
  <u>Agispor Gel</u>: clear gel in an aluminum tube that contains 15 g.
  <u>Agispor Solution</u>: clear to light yellow solution in a brown glass bottle that contains 15 mL of solution.
- Manufacturer and registration holder: Padagis Israel Phamaceuticals Ltd.,1 Rakefet St., Shoham.
- Revised in August 2024 according to MOH guidelines.
- Registration number of the medicine at the National Drug Registry of the Ministry of Health:
  Agispor Gel: 036-81-25610
  Agispor Solution: 036-83-25609