

The medicine is dispensed without a doctor's prescription

AGISTEN ALOEVERA CREAM

Clotrimazole 1%

Inactive and allergenic ingredients 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.

Use this medicine in the correct manner.

Consult the pharmacist if you need further information. Refer to the doctor if symptoms of the illness worsen or if they do not improve after 4 weeks.

1. WHAT IS THE MEDICINE INTENDED FOR?

For the treatment of skin infections caused by dermatophytes or *Candida* strains.

Agisten Aloe vera Cream is intended for the treatment of skin fungi and jock itch. The preparation treats a variety of fungal strains, which may appear in different parts of the body; the feet and toes, armpits, groin, skin folds and other areas of the skin.

Therapeutic group: An antifungal preparation of the imidazole group.

2. BEFORE USING THE MEDICINE

<p>❗ Do not use the medicine:</p> <ul style="list-style-type: none">• if you or your child are sensitive (allergic) to the active ingredient, cetostearyl alcohol or any of the additional ingredients contained in the medicine.• for treatment of infections of the scalp or nails.

Special warnings regarding use of the medicine

As with other creams, Agisten Aloe vera Cream may lower the effectiveness of contraceptives made of rubber, such as a condom or diaphragm. Therefore, if the medicine is intended for use on the genitals, use an alternative contraceptive for at least five days after using this medicine.

Do not use this medicine often or for a prolonged period without consulting a doctor.

Avoid contact of the preparation with the eyes and mouth.

In case of contact with the eyes or mouth, wash thoroughly with water and refer to a doctor.

❗ Before treatment with Agisten Aloe vera Cream, tell the doctor if:

- You are not sure if you (or your baby, in case of a nappy rash) have a fungal infection.
- The patient is sensitive to any food or medicine.

❗ If you or your child 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, trying to become pregnant or breastfeeding, consult with a doctor or medical staff before using the medicine.

If you have already informed the doctor/medical staff, follow their instructions carefully.

❗ Important information about some of the ingredients in the medicine

Agisten Aloe vera Cream contains cetostearyl alcohol that may cause local skin irritation (e.g., rash, itching or redness).

3. HOW SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are uncertain.

If the medicine was prescribed for you by a doctor, follow his/her instructions.

If you purchased the medicine without a prescription, carefully follow the following instructions:

The usual dosage is generally: treatment twice a day (morning and evening) of the affected area.

Instructions for use:

Apply the cream on clean and dry skin and gently massage it into the skin.

Usually, a small amount of ½ cm of cream will suffice to cover an area the size of the palm of your hand.

The duration of treatment depends on the type of infection. In general, the average duration of treatment of different fungal skin infections ranges between 2-3 weeks, however, you may have to use it for a period of 4 weeks.

To avoid recurrence of fungal infections (especially on the legs), continue the treatment for approximately two weeks after disappearance of all signs of the ailment.

The symptoms of the skin infection, such as itching or pain, should improve within a few days of treatment. However, signs such as redness and skin peeling may disappear after a longer period of time. If the symptoms persist, consult the doctor.

Do not exceed the recommended dose.

For external use only.

Do not put the medicine into the mouth or swallow.

Do not cover the treated area with a dressing and/or bandage, unless explicitly instructed to do so by the doctor.

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

If you forget to use the medicine at the required time, use 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, avoid scratching it. Scratching will damage the surface of the skin and cause the infection to spread further.
- Keep the affected areas clean.
- Humidity encourages fungal growth, therefore, keep the affected area dry, but avoid excessive rubbing.
- Wash and dry the affected area before each application of the medicine. Between treatments - talc or antifungal powder can be used to keep the area dry. Consult a doctor or pharmacist for a recommendation of a specific preparation.
- 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. It is recommended to use cotton socks; avoid wearing socks made of wool or synthetic materials. It is recommended to change them a few times a day (depending on the extent of perspiration). 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 appropriate seasons, it is recommended to wear sandals without socks.

Do not take medicines in the dark! Check the label and the dose each time you take the 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 Agisten Aloe vera Cream may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

As with any medicine, some people may be allergic to the medicine. If you or your child are allergic, the reaction will develop immediately after commencing use. If you or your child are experiencing an allergic reaction, discontinue use and seek medical attention immediately. The signs of an allergic reaction can include:

rash, swallowing or breathing problems, swelling of the lips, face, throat or tongue, weakness, nausea, dizziness or fainting.

Likewise, stop treatment and refer to a doctor if, after use, the following occur:

irritation or hypersensitivity, itching, blisters, burning, discomfort, swelling, redness, skin peeling.

In addition, symptoms of a hot sensation and tingling in the treated area may occur. These effects usually pass within a short time, after adaptation to the preparation.

If you or your child experience one of the side effects mentioned above, 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 “Report Side Effects of 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 sight and 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 in a cool place, below 25°C.
- After first opening can be used for 6 months.

6. FURTHER INFORMATION

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

Octyldodecanol, cetostearyl alcohol, cetyl esters wax, sorbitan monostearate, polysorbate 60, benzyl alcohol, aloe vera powder decolorized, purified water.

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

An aluminum tube that contains 20 grams of white cream.

- 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 May 2015.

- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 4317.22461