

Patient package insert in accordance with the pharmacists' regulations (preparations) - 1986

The medicine is dispensed with a doctor's prescription only

Hydroagisten Cream

Clotrimazole 1%, Hydrocortisone Acetate 1%

Inactive ingredients and allergens in the medicine - see in section 2 "Important information regarding some of the ingredients of the medicine" and section 6 of the leaflet.

Read this entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for your treatment. Do not pass it on to others. It may harm them even if you think that their medical condition is similar.

Refer to the doctor if the symptoms of the disease worsen or do not improve after 7 days.

1. What is the medicine intended for?

For treatment of skin inflammations involving fungal infections.

Therapeutic group:

Hydrocortisone acetate is a mild steroid that reduces swelling, redness, and itching associated with skin infection.

Clotrimazole belongs to the imidazoles group-antifungal preparations that fight the cause of fungal skin infections.

2. Before using the medicine

Do not use the medicine:

- if you (or your infant, if treating nappy rash) are hypersensitive (allergic) to the active ingredients clotrimazole and hydrocortisone acetate or to any of the other ingredients contained in the medicine, including cetostearyl alcohol (see section 6).
- on areas of broken skin.
- on large areas of skin (more than 5-10% of body surface).
- for longer than 7 days.
- to treat cold sores or acne.
- on any untreated bacterial skin infection, such as syphilis or tuberculosis.
- for vaccination skin reactions.
- for the treatment of shingles, chicken pox, rosacea, or herpes.

If you are unsure about any of these restrictions, speak to your doctor about it.

Special warnings regarding use of the medicine

- As with all steroids, long-term, continuous use on large areas of skin should be avoided, particularly in infants and children.

- Do not cover the area being treated with a dressing or bandage.
- In infants, care should be taken not to fasten nappies too tightly over the treated area, as fastening too tightly may increase the absorption of the hydrocortisone acetate.
- Wash your hands immediately after applying the cream.
- As with other creams, Hydroagisten Cream may reduce the effectiveness of rubber contraceptives, such as a condom or diaphragms. Consequently, if this cream is intended for use on the genitals, use alternative contraceptives for at least five days after using this medicine.
- Contact your doctor if you experience blurred vision or other visual disturbances.

Drug interactions

If you are taking or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

Pregnancy, breastfeeding, and fertility

If you are pregnant, breastfeeding or trying to become pregnant, tell the doctor before using Hydroagisten Cream. If you have been for a consultation, follow the doctor's instructions carefully.

Important information about some of the ingredients of the medicine

This medicine contains cetostearyl alcohol which may cause local skin irritation (such as: a rash, itching or redness), and benzyl alcohol which may cause mild local irritation and allergic reactions.

3. How should you use the medicine?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and manner of treatment with the medicine.

The dosage and manner of treatment will be determined by the doctor only.

The usual recommended dosage is: Application of a thin layer of Hydroagisten on the affected area twice daily.

Directions for use:

Adhere to the following instructions unless the doctor directed you otherwise:

- Before use, unscrew the cap to open the tube and pierce the tube seal with the piercer in the cap.
- If the feet are infected, they should be washed and dried thoroughly before using the cream, especially between the toes.
- Apply a thin and even layer of Hydroagisten Cream to the affected areas twice daily and gently rub into the skin. Approximately 1 cm of cream per application should be enough.
- Do not cover the area being treated with a dressing or bandage.

- As with all products containing hydrocortisone, wash your hands immediately after applying the cream.

Treatment duration should not exceed 7 days.

The symptoms of skin infection, such as itching or pain, should improve within a few days of treatment. However, signs such as redness and scaling (skin peeling) may take longer to disappear. If the symptoms persist or do not improve after 7 days, consult the doctor.

Do not exceed the recommended dose. For external use only.

Do not put the medicine in the mouth or swallow it.

If you have accidentally swallowed the cream, proceed immediately to your doctor or a nearby hospital.

If the cream accidentally entered the eyes or mouth, immediately wash them thoroughly with water and contact the doctor.

If you have accidentally taken a higher dosage, if you have taken an overdose, or if a child or someone else accidentally swallowed the medicine, proceed immediately to a doctor or to a hospital emergency room and bring the package of the medicine with you.

If you forgot to apply the cream at the scheduled time, apply it as soon as possible and continue treatment as usual. Continue with the treatment as recommended by the doctor.

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

You can contribute to the success of the treatment if you follow these tips:

- Although the affected area will itch, try to avoid scratching it. Scratching will cause damage to the surface of the skin, thereby causing the infection to spread further.
- Keep the affected area clean.
- Dry the skin thoroughly, but avoid excessive rubbing.
- Do not share towels, bathmats, etc. with other people as you could spread the infection to them.
- Wash your hands after use to prevent the infection from spreading.
- Moisture enhances fungal growth, so the affected area should be kept dry.
- Wash the affected skin before each application of the medicine. Between treatments with the cream an antifungal powder can be used to dry the area.

If you suffer from fungal infection of the feet:

- Be careful to dry the skin between the toes thoroughly.
- Thoroughly wash socks, stockings, and tights in hot water to remove all of the shed skin or the fungal spores. It is preferable to use cotton socks; avoid wearing socks made from wool or from synthetic materials.

- It is preferable to change them a few times a day (according to the amount of sweat).
- If possible, change your shoes every day. 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 a medicine. Wear glasses if you need them.

4. Side effects

As with any medicine, use of Hydroagisten Cream 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 any medicine, some people may be allergic to the cream. If you are or your infant is allergic, an allergic reaction will occur soon after beginning use. If you or your infant experience an allergic reaction, **stop treatment with Hydroagisten Cream and proceed immediately to a doctor or the nearest hospital emergency room.** The signs of an allergic reaction may include:

- Rash.
- Swallowing or breathing problems.
- Swelling of the lips, face, throat, or tongue.
- Weakness, feeling dizzy or faint.
- Nausea.

After applying the cream you may experience:

Itching, rash, blisters, burning, discomfort, swelling, irritation, redness or peeling of the skin, blurred vision.

The treatment should be limited to 7 days, unless advised otherwise by the doctor. In cases when the cream is being applied to large areas of the skin, under a dressing, or for a period of time of more than two weeks, you may experience the following skin reactions:

- Varicose veins (broken veins).
- Increased hair growth.
- Stretch marks.
- Thinning or whitening of the skin.
- Secondary infections.
- Acne-like rash.

If a side effect has appeared in you or your infant, if one of the side effects worsens, or if you or your child suffer from a side effect not mentioned in this leaflet, consult the doctor.

Reporting Side Effects:

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects from Drug Treatment" that can be found on the Ministry of Health website (www.health.gov.il), directing to the online form of adverse events reporting or via the following link:

<https://sideeffects.health.gov.il>

Additionally, 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 must be kept 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 doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package and tube. The expiry date refers to the last day of that month.
- Store in a cool place below 25°C.
- Can be used for 6 months after the first opening, but not later than the expiration date.
- Do not dispose of medicines via wastewater or household waste. Ask the pharmacist how to dispose of medicines you no longer need. These measures will help protect the environment.

6. Further information

- In addition to the active ingredients, the medicine also contains: Purified water, 2-Octyldodecanol, Cetostearyl alcohol, Cetyl esters wax, Sorbitan monostearate, Polysorbate 60, Benzyl alcohol. The tube contains 150 mg Benzyl alcohol. See section 2 "Do not use the medicine:" and "Important information about some of the ingredients of the medicine" regarding the ingredients Cetostearyl alcohol and Benzyl alcohol.
- **What the medicine looks like and the contents of the package:** An aluminum tube containing 15 grams of off-white cream.
- **Manufacturer, registration holder, and address:** Perrigo Israel Pharmaceuticals Ltd., P.O.B. 16, Yeruham.
- Revised in April 2021 according to MOH guidelines.
- **Registration number of the medicine in the National Drug Registry of the Ministry of Health:** 4282.24888.