

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% w/w

Hydrocortisone Acetate 1% w/w

Inactive and allergenic ingredients in the medicine – see section 2 "Important information about some of the ingredients in the medicine" and section 6 "Further information".

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.

Refer to the doctor if the symptoms worsen or are not improving after 7 days.

1. WHAT IS THIS MEDICINE INTENDED FOR?

For the treatment of skin inflammations that involve a fungal infection.

Therapeutic group:

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

Clotrimazole belongs to the imidazole group – antifungal preparations that fight the cause of fungal skin infections.

2. BEFORE USING THE MEDICINE

Do not use this medicine:

- if you (your infant or child) are sensitive (allergic) to the active ingredients clotrimazole and hydrocortisone acetate, or to any of the additional ingredients contained in the medicine, including benzyl alcohol, cetostearyl alcohol (see section 6 "Further information").
- on areas of broken skin.
- on extensive areas of skin (more than 5-10% of the 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 treatment of shingles, chicken pox, rosacea, or herpes.

Special warnings regarding use of the medicine

- As with all steroidal medicines, prolonged long-term use on extensive 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 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 the doctor if you experience blurred vision or other visual disturbances.
- Do not smoke or come close to an open fire source due to risk of severe burns. Fabric (clothing, linens, dressings, and the like) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and linens may reduce product build-up, but not totally remove it.

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 are trying to become pregnant, tell the doctor before using Hydroagisten Cream.

If you consulted, follow the doctor's instructions carefully.

Important information about some of the ingredients in the medicine

The medicine contains cetostearyl alcohol, which may cause localized skin irritation (e.g., contact dermatitis), and about 10 mg benzyl alcohol per 1 gram medicine, which may cause mild localized irritation and allergic reactions.

3. HOW SHOULD THE MEDICINE BE USED?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the medicine. The dosage and treatment regimen will be determined by the doctor only.

The recommended dosage is usually:

Apply a thin layer of Hydroagisten Cream on the affected area twice a day.

Instructions for use:

Adhere to the following instructions, unless instructed otherwise by the doctor:

- Before use, unscrew the cap to open the tube and pierce the tube seal with the piercer in the cap.
- If feet are infected, wash and thoroughly dry them 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 soreness, should improve within a few days of treatment. However, signs such as redness and 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 dosage.**

For external use only.

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

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

If you accidentally took a higher dosage, if you took an overdose, or 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 cream at the scheduled time, apply it as soon as possible and continue treatment as usual.

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.

You can contribute to the success of the treatment if you follow the following advice:

- Even though the affected area will be itchy, try to avoid scratching. Scratching will cause damage to the surface of the skin and thereby cause continued spread of the infection.
- Keep the affected area clean.
- Thoroughly dry the skin, but avoid excessive rubbing.
- Do not share towels, shower mats and the like with other people, as the infection may pass on to them.
- Wash your hands after use to avoid spread of the infection.

If you suffer from a fungal infection on your feet:

- Be careful to thoroughly dry the skin between the toes.
- Thoroughly wash socks, stockings and tights in hot water to remove all of the shed skin or the fungal spores.

• If possible, change your shoes every days.

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 Hydroagisten Cream may cause side effects in some users. Do not be alarmed by the list of side effects. You may not experience any of them.

As with all medicines, some people may be allergic to the cream. If you, your infant or your child is allergic, a reaction will develop soon after beginning use. If you, your infant or your child experiences an allergic reaction, **stop treatment with Hydroagisten Cream and refer immediately to a doctor or proceed to the hospital emergency room closest to you.**

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 instructed 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.
- whitening or thinning of the skin.
- secondary infections.
- acne-like rash.

If a side effect occurs to you, your infant or your child, if one of the side effects worsens, or if you, your infant or your child suffers from a side effect not mentioned in the 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://sideeffects.health.gov.il>

In addition, they can be reported to Padagis via the following address: Padagis.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 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 first opening, but no later than the expiry date.
- Caution! Flammable material. Do not light a cigarette or expose to fire until the product has fully dried.

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.

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

An aluminum tube that contains 15 grams of off-white cream.

- **Registration holder and manufacturer:** Padagis Israel Pharmaceuticals Ltd., 1 Rakefet St., Shoham.
- Revised in May 2024 in accordance with the Ministry of Health guidelines.
- **Registration number of the medicine in the National Drug Registry of the Ministry of Health:** 42-82-24888

30200764 05.2024 SH108590 PL v1