

**PATIENT PACKAGE INSERT
IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS
(PREPARATIONS) – 1986**

The medicine is dispensed with a doctor's prescription only.

Comagis Cream

Each 100 grams of Comagis Cream contains:

1 gram bifonazole

0.05 grams flucinonide

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

Read the 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 for 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 THE MEDICINE INTENDED FOR?

Comagis Cream relieves conditions of inflammation accompanied by fungal infection that respond to corticoid therapy.

Therapeutic group: Anti-inflammatory + antifungal.

2. BEFORE USING THE MEDICINE

Do not use the medicine:

- If you are sensitive (allergic) to the active ingredients or any of the additional ingredients contained in the medicine (see section 6).
- To treat diaper rash. If your infant has diaper rash, refer to the doctor to receive appropriate treatment.
- To treat nail or scalp infections.
- To treat vaginal infections.
- Do not use the medicine on large areas of the body or for a long time.

Special warnings regarding use of the medicine

- Do not allow the medicine to come in contact with the eyes.
- Do not bandage, cover or wrap the treated area in a manner that will create an occlusive dressing, unless directed to do so by a doctor.

Before treatment with Comagis Cream, tell the doctor if

- you have ever experienced an allergic reaction to any antifungal substance.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular, inform the doctor or pharmacist if you are taking warfarin (an anticoagulant).

Pregnancy, breastfeeding and fertility

Do not use the medicine if you are pregnant or breastfeeding, unless recommended by the doctor. There is no information about the effect of using Comagis Cream on fertility – consult with the doctor before use.

Use in children and infants

For children being treated in the diaper area, do not use tight-fitting diapers or plastic underwear, as these garments constitute an occlusive dressing.

Children may absorb relatively larger amounts of topical corticosteroids and therefore, may be more sensitive to systemic toxicity. If irritation develops, stop the treatment.

Important information about some of the ingredients of the medicine

The medicine contains cetosteryl alcohol, which may cause local skin irritation (e.g., rash, itching or redness).

The medicine contains 10.36 mg of benzyl alcohol per 1 gram of cream. Benzyl alcohol may cause an allergic reaction and mild local irritation.

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 uncertain about the dosage and treatment regimen of the medicine.

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

Instructions for use:

- Before using the medicine, pierce the tube seal by inverting the cap, and pressing it into the end of the tube.
- Before applying the cream, wash and dry the affected area thoroughly, especially between the toes in case of foot infection.
- Apply a thin, even layer of the cream to the affected area once a day, preferably at night before going to sleep, and gently massage into the skin.
- The duration of the treatment will be determined by the doctor.
- In case of foot infection, it is advisable to also use an antifungal powder. Consult the doctor or pharmacist to have them recommend a specific preparation.

Symptoms of skin infection, such as itching or pain, should improve within a few days of treatment. However, signs such as redness and skin peeling may take more time to disappear. If the symptoms do not improve within 7 days, consult the doctor.

Do not exceed the recommended dose.

For external use only.

Do not put the cream in your mouth or swallow it. If the medicine accidentally comes in contact with the mouth or eyes, wash immediately with water and refer to a doctor.

If a child or someone else has accidentally swallowed the medicine, refer immediately 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 at the required time, apply the medicine as soon as possible and continue the treatment as usual.

Adhere to the treatment regimen as recommended by the doctor.

How can you contribute to the success of the treatment?

- Although the affected area will itch, try to avoid scratching it. Scratching will damage the surface of the skin and will thus cause

the infection to spread even further.

- Keep the affected areas clean.
- Moisture encourages the growth of fungus. The affected area should therefore be kept dry.
- Wash the affected area before every application of the medicine. Between treatments – an antifungal powder can be used to dry the area.
- Always wash your hands after treating the infection in order to prevent its spread.
- Do not share towels, bath mats, etc. with others as the infection may spread to them.
- If the treatment is for your feet – pay attention to thoroughly wash and dry, especially between the toes. However, excessive rubbing should be avoided. It is advisable to use cotton socks; avoid wearing socks made of wool or synthetic materials. It is advisable to change socks several times a day (depending on the amount of sweat).
- Thoroughly wash the socks, nylon stockings and tights in hot water to remove any shed skin or fungal spores.
- Change your shoes daily if possible.
- In the relevant seasons, it is recommended to wear sandals without socks.
- If you are planning to stop using the medicine, discuss the implications of this with the doctor before stopping.

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 Comagis 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.

Inform the doctor of any sign of a local side effect, especially under an occlusive dressing.

As with any medicine, there are people who may be allergic to the medicine. If you are allergic, the reaction will develop immediately after you start using it. If you experience an allergic reaction, stop using the medicine and refer immediately to a doctor or proceed to the nearest hospital emergency room.

Signs of an allergic reaction may include:

- Rash.
- Problems swallowing or breathing.
- Swelling of the lips, face, throat or tongue.
- Weakness, dizziness or fainting.
- Nausea.

After applying the cream, you may experience one of the following symptoms:

- Mild irritation or burning.
- Skin redness.
- Peeling.

If the effects are intolerable, stop treatment and consult with the doctor as soon as possible.

The medicine may cause local skin irritation that is very similar to symptoms of infection. If any of the symptoms get worse, stop treatment and refer to the doctor as soon as possible.

These symptoms may include:

- Burning, pain or itching.
- Rash, redness, dryness.
- Soft or soggy appearance of the skin.
- Swelling, hives (red, raised and itchy lesions), blisters.

The following side effects are rarely reported when using topical corticosteroids, but may occur more frequently when using an occlusive dressing:

Burning, itching, irritation, dryness, folliculitis, hypertrichosis in women (of non-hormonal origin), acneiform eruptions, hypopigmentation, skin inflammation around the mouth, allergic contact dermatitis, softening of the skin, secondary infection, skin atrophy, stretch marks, miliaria.

If a side effect occurs, or if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult the doctor.

Reporting of 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>

Additionally, a report can be made to Padagis Israel Pharmaceuticals Ltd. using 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. The expiry date refers to the last day of that month. After first opening, the medicine may be used for 6 months, but no later than the expiry date.
- Store below 25°C.
- Store in the original package.
- Do not dispose of medicines via wastewater or household waste. Ask the pharmacist how to dispose of medicines not in use. These measures will help to protect the environment.

6. FURTHER INFORMATION

- In addition to the active ingredients, the medicine also contains: Cetosteryl alcohol, 2-oclydodecanol, cetyl esters wax, sorbitan monostearate, polysorbate 60, benzyl alcohol, purified water.
- What the medicine looks like and contents of the package: An aluminum tube containing 7 or 15 grams of white cream.
- Name of manufacturer and registration holder: Padagis Israel Pharmaceuticals Ltd., 1 Rakefet St., Shoham.
- Revised in May 2023 according to MOH guidelines.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 063.04.26742