Patient Package Insert in Accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine can be sold with a physician's prescription only

Comagis Cream

Each 100 grams of Comagis Cream contains:
1 gram Bifonazole
0.05 grams Fluocinonide
Inactive ingredients and allergens in the medicine - see in section 6 "Additional information" and in section 2 "Important information about some of the ingredients of this medicine".

Read this entire leaflet carefully before using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask the physician 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 the same as yours.

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 hypersensitive (allergic) to the active ingredients or to any of the other ingredients this medicine contains (see section 6).
- To treat nappy rash. If your infant has nappy rash, refer to the physician to receive a suitable treatment.
- To treat nail or scalp infections.
- To treat vaginal infections.
- On large areas of the body or for a long time.

Special warnings regarding the use of the medicine
- Do not let the medicine come in contact with the eyes.
- Do not bandage, cover or wrap the treated area so that an occlusive dressing is formed unless directed by the physician.

Before the treatment with Comagis Cream tell the physician 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 physician or pharmacist. Especially inform the physician or pharmacist if you are taking warfarin (an anticoagulant).

Pregnancy and breastfeeding
Do not use this medicine if you are pregnant or breastfeeding, unless recommended by the physician.

Use in children and infants
Do not use tight-fitting diapers or plastic pants on children being treated in the diaper area, as these garments constitute an occlusive dressing.
Children may absorb relatively larger amounts of topical corticosteroids and therefore may be more sensitive to systemic poisoning. If irritation develops stop the treatment.

Important information about some of the ingredients of this medicine
The medicine contains cetostearyl 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 to use the medicine

Always use according to the physician's instructions.
Check with the physician or pharmacist if you are not sure.
The dosage and treatment regimen will be determined by the physician 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 feet infection.
- Apply a thin and 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 treatment will be determined by the physician.
- In case of feet infection, it is advisable to also use an antifungal powder. Consult the physician or pharmacist for a recommendation on a specific product.

Symptoms of skin infection, such as itching or pain, should improve within a few days of treatment. However, symptoms such as redness and skin peeling may take more time to disappear . If the symptoms do not improve within 7 days, consult the physician.
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 the physician.
If a child or someone else has accidentally swallowed the medicine, proceed immediately to the physician or to a hospital emergency room and bring the medicine package with you.

If you forgot to apply the medicine at the set time, apply the cream as soon as possible and continue the treatment as usual.
Continue with the treatment as recommended by the physician.

How can you assist in 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 thus will cause the infection to spread even further.
- Keep the affected areas clean.
- Moisture encourages the growth of fungus. Therefore keep the affected area 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, avoid excessive rubbing. 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 (according to 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 appropriate seasons it is recommended to wear sandals without socks.

Do not take medicines in the dark! Check the label and the 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 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 physician on any sign of local side effects, 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 proceed immediately to the physician or to the nearest hospital emergency room.
Signs of an allergic reaction may include:
- Rash.
- Swallowing or breathing problems.
- 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:
- Slight irritation or burning.
- Skin redness.
- Peeling.

If the effects are intolerable, stop the treatment and refer to the physician as soon as possible.

The medicine may cause local skin irritation that is very similar to symptoms of infection. If any of the symptoms gets worse, stop the treatment and refer to the physician as soon as possible.
These symptoms may include:
- Burning, pain or itching.
- Rash, redness, dryness.
- Soft or soggy appearance to the skin.
- Swelling, hives (red, raised and itchy lesions), blisters.

The following side effects are rarely reported when using topical corticosteroids, but they may occur more frequently when using an occlusive dressing:
Burning, itching, irritation, dryness, folliculitis, hypertrichosis in women (which is not caused by a hormonal source), acneiform eruptions, hypopigmentation, skin inflammation around the mouth, allergic contact dermatitis, softening of the skin, secondary infection, skin atrophy, striae, miliaria.
If a side effect appears, if one of these side effects gets worse, or if you suffer from a side effect not mentioned in this leaflet, consult the physician.

Reporting of side effects:
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 (www.health.gov.il) directing to the online form of adverse events reporting or by clicking on the following link: https://sideeffects.health.gov.il
Additionally, side effects can be reported to Perrigo via the following address: www.perrigo-pharma.co.il

5. How to store the medicine

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the sight and reach 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.
- After first opening, the medicine can be used for 6 months, and not later than the expiry date.
- Store below 25°C.
- Store in the original package.
- Medicines should not be disposed of via wastewater or household waste. Ask the pharmacist how to dispose of medicines no longer in use. These measures will help to protect the environment.

6. Additional information

- In addition to the active ingredients, the medicine also contains:
  Cetostearyl alcohol, 2-octyldodecanol, cetyl esters wax, sorbitan monostearate, polysorbate 60, benzyl alcohol, purified water.
- What does the medicine look like and what is the contents of the package: An aluminum tube that contains 7 or 15 grams of white cream.
- Manufacturer and registration holder: Perrigo Israel Pharmaceuticals Ltd., P.O.B.16, Yeruham.
- Revised in May 2021 according to MOH guidelines.
- Registration number of the medicine at the National Drug Registry of the Ministry of Health: 063.04.26742

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