

**PATIENT PACKAGE INSERT IN ACCORDANCE  
WITH THE PHARMACISTS' REGULATIONS**

**(PREPARATIONS) – 1986**

The medicine is dispensed without a doctor's prescription

# FUNGIVERA CREAM

## Clotrimazole 1%

Inactive and allergenic ingredients in the product – see section 2 'Important information about some of the ingredients in the medicine' and section 6 in the leaflet.

**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 the product according to the instructions in the dosage section (3) in this leaflet. Consult the pharmacist if you need further information.

Refer to the doctor if signs of the illness (symptoms) 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* species.

Fungivera Cream is intended for the treatment of skin fungi and jock itch. The product treats a variety of fungal strains, which may appear in different areas of the body: the feet and toes, armpits, groin, skin folds and other areas of the skin.

**Therapeutic group:** An antifungal product of the imidazole group.

### 2. BEFORE USING THE MEDICINE

#### **Do not use the medicine:**

- If you are sensitive (allergic) to the active ingredient clotrimazole or to 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, Fungivera Cream may lower the effectiveness of contraceptives made of rubber, such as a condom or diaphragm. Therefore, if Fungivera Cream is intended for use on the genitals, use an alternative contraceptive for at least five days after using this product. Do not use this product often or for a prolonged period without consulting a doctor.

Avoid contact of the product 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 Fungivera 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.

#### **Drug interactions**

**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, if you are trying to become pregnant or are breastfeeding, consult the doctor or pharmacist before using the product.

#### **Important information about some of the ingredients in the medicine**

Fungivera Cream contains cetostearyl alcohol, which may cause localized skin irritation (rash, itching or redness) and benzyl alcohol, which may cause mild localized irritation and allergic reactions.

### 3. HOW SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are uncertain about the product dosage and instructions for use.

If the product was prescribed for you by a doctor, always use it in accordance with the doctor's instructions.

If you purchased the product without a doctor's prescription, use it in accordance with the instructions in this section:

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 with the doctor.

**Do not exceed the recommended dose.**

**For external use only.**

**Do not put the medicine into the mouth or swallow it.**

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 product** 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 cream. 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 product.

- 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 a 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 Fungivera 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 all medicines, 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 may 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 product.

**If a side effect occurs, if one of the side effects worsens, or if you suffer 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](http://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, you can report to Perrigo via the following address:

[www.perrigo-pharma.co.il](http://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 reach and sight 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.

- Distributed by: Super-Pharm (Israel) Ltd., 16 Aryeh Shenkar, Herzliya 4672516

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- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 165-90-36618.