

**Patient leaflet in accordance with the Pharmacists' Regulations
(Preparations) – 1986**

This medicine can be sold without a physician's prescription

Fungivera Cream

Active ingredient:

Clotrimazole 1% w/w

Inactive ingredients and allergens in the product - see section 2 "Important information about some of the ingredients of this product" and section 6 "Additional information".

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

Use this product according to the instructions in the dosage section in this leaflet.

Consult the pharmacist if you need additional information. Contact a physician if the symptoms of your illness get worse or if they do not improve after 4 weeks.

1. What is the medicine intended for?

Fungivera Cream is used to treat skin and mucous tissue infections caused by various types of fungi. It is also used to treat candida infections of the vagina and of the penis.

Therapeutic Group: Antifungal agents for local use of the Imidazole group.

2. Before using the medicine

Do not use the medicine:

- If you are hypersensitive (allergic) to the active ingredient or to any of the other ingredients that this medicine contains, including cetostearyl alcohol (see section 2 "Important information about some of the ingredients of this medicine and section 6 "Additional information").
- For treatment of nail fungus or on the scalp.

Special warnings regarding the use of the product:

As with other creams, Fungivera Cream may reduce the effectiveness of contraceptives made of rubber such as a condom or diaphragm. If you use Fungivera Cream on the vagina or penis, alternative contraceptives should be used for at least 5 days after the use of this product.

If your condition has not improved within 4 weeks, contact a physician.

Drug Interactions:

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

Pregnancy, breastfeeding and fertility:

If you are pregnant, if you are breastfeeding or trying to conceive, consult a physician or pharmacist before using this product.

Driving and using machines:

Fungivera Cream does not affect the ability to drive or use machines or only has a negligible effect.

Important information about some of the ingredients of this medicine:

Fungivera Cream contains cetostearyl alcohol which can cause local irritation of the skin (rash, itching or redness).

Fungivera Cream contains 10 mg benzyl alcohol per 1 gram of cream which can cause an allergic reaction.

3. How to use the medicine

You should check with your physician or pharmacist if you are not sure about your dose or about how you should use this medicine. If this product has been prescribed for you by your physician, follow any instructions your physician may have given you. If you purchased this product without a prescription, it is to be used as described in this section.

The usual dosage is generally: 2-3 treatments a day.

How to use:

- Instructions for opening – in order to open the tube, the stopper should be turned up-side-down and then pierce the seal of the tube by pressing the stopper.
- For treatment of athlete's foot: Before applying the cream, rinse the feet and dry well, especially between the toes.
- Apply a thin, uniform layer on the infected areas 2 to 3 times a day and rub the cream into the skin by massage.
- Typically, a small amount of ½ cm will be enough to treat a palm-sized area.
- The duration of treatment of fungal skin infections depends on the type of infection. Usually, the duration of treatment is at least 2 weeks, although it may take up to 4 weeks of treatment.
- If you suffer from athlete's foot, it is recommended to use an anti-fungal powder. Consult a physician or pharmacist.
- The symptoms of skin infection such as itching and pain are expected to improve within a few days of treatment, but symptoms such as redness and peeling of the skin may disappear after a longer period of time.
- If your condition has not improved within 4 weeks, contact your physician.

Do not exceed the recommended dose.

For external use only.

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

- If you accidentally swallowed the product, you should contact your physician immediately or go to the emergency room at the nearest hospital.
- Avoid contact of the product with the eyes or mouth. In case of contact with the eyes, rinse well with water and consult a physician.
- **If you have accidentally taken a higher dosage**, if you have taken an overdose or if a child or someone else has swallowed the medicine by mistake, proceed immediately to a physician or to the emergency room of a hospital and take the medicine package with you.
- **If you forget to apply the product on time**
 - Apply immediately as soon as you have remembered and continue the rest of the treatment as usual.
- **How can you contribute to the success of the treatment?**
 - Although the affected area is itchy, avoid scratching the area. Scratching may cause damage to the skin surface and thus spread the infection.
 - Keep infected areas clean.
 - Dry the area thoroughly but avoid excessive rubbing.
 - Do not share towels, bath mats etc. with other people as they may get the infection.
 - Always wash your hands after treating the infection to prevent its spread.
- If you suffer from athlete's foot:
 - Be sure to dry the skin between the toes thoroughly.

- Wash your socks and stockings/tights thoroughly in hot water to remove any shed skin or fungal spores.
- Change your footwear daily if possible.

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 any further questions about the use of the medicine, ask your physician or pharmacist.

4. Side effects

Like all medicines, the use of Fungivera Cream may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not suffer from any of them.

As with all medicines, some patients may be hypersensitive (allergic) to this cream. If you are allergic, a reaction will develop soon after using this product. **Discontinue treatment and contact a physician or proceed to a hospital emergency room immediately if** an allergic reaction develops. Signs of allergic reaction may include:

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

After using the medicine you may experience one of the following symptoms: itching, rash, blisters, burning, discomfort, swelling, irritation, redness or peeling of the skin.

If a side effect appears, if one of the side effects gets worse, or if you suffer from a side effect which is not mentioned in this leaflet, consult the physician.

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 homepage 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 Padagis via the following address: Padagis.co.il

5. How to store the medicine?

- 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 to avoid poisoning. Do not induce vomiting without an explicit instruction from 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.
- **Storage conditions:**
 - Store in a cool place, below 25°C.
 - After first opening, the medicine can be used for 6 months and not later than the expiry date that appears on the package.

6. Additional information

- In addition to the active ingredient, Fungivera Cream also contains: Octyldodecanol, cetostearyl alcohol, cetyl esters wax, sorbitan monostearate, polysorbate 60, benzyl alcohol, aloe vera powder decolorized, purified water.
- What does the medicine look like and what is the contents of the package:

- Fungivera Cream is a white cream packaged in an aluminum tube that contains 20 grams.
- Manufacturer and registration holder: Padagis Israel Pharmaceuticals Ltd., 1 Rakefet St., Shoham.
- Revised in January 2023 according to MOH guidelines.
- Registration number of the medicine at the National Drug Registry of the Ministry of Health: 165-90-36618-99

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