

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

This medicine is dispensed without a doctor's prescription

Canesten®

Cream



Active ingredient:

Clotrimazole 1%

Inactive ingredients and allergens: see section 2 under "Important information about some of this medicine's ingredients" and section 6 "Additional information".

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, consult your doctor or pharmacist.

Use this medicine according to the instructions in the section about dose in this leaflet. Consult a pharmacist if you need further information. Contact your doctor if your disease symptoms get worse or do not improve within 4 weeks.

1) What is this medicine intended for?

Canesten® cream is used to treat skin and mucous membrane infections caused by various types of fungi. It is also used to treat candida infection of the vagina and of the penis.

Therapeutic group: imidazole antifungal agents for local use.

2) Before using the medicine

Do not use this medicine:

- If you are sensitive (allergic) to the active ingredient or to any of the other ingredients in this medicine, including cetostearyl alcohol (see section 6, "Additional information").
- To treat fungal infection of the nails or on the scalp.

Special warnings about using the medicine:

Do not smoke or go near a source of naked flames due to the risk of severe burns. Fabric (clothing, bedding, dressings, etc.) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it. As with other creams, Canesten® cream may reduce the effectiveness of contraceptives made of rubber such as condoms or diaphragms. If you use this product in the vagina or on the penis, alternative contraceptives should be used for at least 5 days after using this product. If your condition has not improved within 4 weeks, contact a doctor.

Drug interactions:

If you are taking or have recently taken any other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.

Pregnancy, breastfeeding, and fertility

Pregnancy and breastfeeding:

If you are pregnant, if you are breastfeeding or trying to conceive, consult your doctor or pharmacist before using this medicine, and follow his/her instructions. You may only use this medicine during pregnancy under the supervision of a doctor.

You may use this medicine while breastfeeding, but if used on the nipple area, wash your nipple area before breastfeeding.

Fertility:

There is no information indicating fertility problems due to using this medicine.

Driving and using machines

Canesten® cream has no or negligible effect on the ability to drive or use machines.

Important information about some of this medicine's ingredients:

This medicine contains cetostearyl alcohol which can cause a local reaction of the skin such as contact dermatitis. This medicine contains 20 mg benzyl alcohol in each gram of product; benzyl alcohol may cause allergic reactions and mild local irritation.

3) How to use this medicine

Check with your doctor 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 a doctor, follow any instructions he/she may have given you. If you purchased this product without a prescription, use it as described in this section.

The recommended dosage is usually:

Apply 2 to 3 times a day.

Taking the medicine:

- Instructions for opening - To open the tube, invert the cap and pierce the seal of the tube by pressing the cap down.
- To treat athlete's foot: Before applying the cream, rinse the feet and dry well, especially between the toes.
- Apply a thin, uniform layer on the affected areas 2 to 3 times a day and rub the cream into the skin.
- A small amount of ½ cm will usually be enough to treat a palm-sized area.
- If you suffer from athlete's foot, it is advisable to also use an anti-fungal powder. Consult your doctor or pharmacist.
- The symptoms of skin infection such as itching or soreness should improve within a few days of treatment, although symptoms such as redness and scaling may take longer to disappear.

Duration of treatment:

- **The duration of treatment** of fungal skin infections depends on the type of infection. In most cases, the duration of treatment is at least two weeks, although it may take up to 4 weeks of treatment.
- If your condition has not improved within 4 weeks, contact a doctor.

Do not exceed the recommended dose.

For external use only. Do not put the medicine in your mouth or swallow it. If you accidentally swallow the medicine, contact a doctor immediately or go to the emergency room at the nearest hospital. Avoid contact of the medicine with the eyes or mouth. In case of contact with the eyes or mouth, rinse well with water and consult a doctor.

If you have accidentally taken a higher dose. If you have taken an overdose or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to apply the medicine on time, apply the cream as soon as you remember and continue the rest of the treatment as usual.

- **How can you help your treatment work?**

- Although the affected area is itchy, avoid scratching the area. Scratching may damage the skin surface and cause the infection to spread.
 - Keep the affected areas clean.
 - Dry the area thoroughly but avoid excessive rubbing.
 - Do not share towels, bath mat etc. with other people as the infection could spread to them.
 - Always wash your hands after treating the infection to prevent it from spreading.
- If you suffer from athlete's foot:
 - Be sure to dry the skin between your 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 every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4) Side effects:

Like all medicines, using Canesten® cream may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience 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 your doctor immediately or go to an emergency room at the nearest hospital** 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: itching, rash, blisters, burning sensation, discomfort, swelling, irritation, pins and needles, redness or peeling of the skin.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link "Reporting side effects of drug treatment" on the Ministry of Health home page (www.health.gov.il), which links to an online form for reporting side effects. You can also use this link:

<https://sideeffects.health.gov.il>

5) How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
 - Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:**
 - Store below 30°C.
 - Do not use for longer than 3 months after opening.

6) Additional information

- **In addition to the active ingredient, this medicine also contains:**
Purified water, octyldodecanol, cetostearyl alcohol, cetyl palmitate, benzyl alcohol, sorbitan stearate, polysorbate 60.

See under “Special warnings about using this medicine” with regard to cetostearyl alcohol and benzyl alcohol.

- **What Canesten® cream looks like and contents of the pack:**
Canesten® cream is a white cream, packaged in a tube containing 20 or 30 grams. Not all pack sizes may be marketed.
- **Name and address of marketing authorisation holder/importer:** Bayer Israel Ltd., 36 Hacharash St., Hod Hasharon 45240.
- Revised in October 2022 according to MoH guidelines.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 149-44-33680-01.