

The medicine is dispensed without a doctor's prescription

Canesten® Cream



Active ingredient:

Clotrimazole 1%

Excipients: See section 2 "Important information about some of the medicine ingredients" and section 6 "Additional Information".

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

You must use the preparation according to the instructions in the dosage section of this leaflet. Consult a pharmacist if you need more information. You must contact a doctor if the disease symptoms exacerbate or do not improve after 4 weeks.

1) What the medicine is used for?

Canesten® 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 vulva 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 sensitive (allergic) to the active ingredient or to any of the other ingredients that this medicine contains, including cetostearyl alcohol (see section 6 - "Additional Information").
- For treatment of nail fungus or on the scalp.

Special warnings regarding the use of the medicine:

As with other creams, Canesten® cream may reduce the effectiveness of contraceptives made of rubber such as a condom or diaphragm. If you use this preparation on the vagina or penis, alternative contraceptives should be used for at least 5 days after the use of this preparation. If your condition has not improved within 4 weeks, contact a doctor.

Drug interactions:

Tell the doctor or pharmacist if you are taking, or have recently taken any other medicines including non-prescription medications and food supplements.

Pregnancy and breastfeeding:

If you are pregnant, if you are breastfeeding or trying to conceive, consult your doctor or pharmacist before using this preparation.

Driving and using machines:

Canesten® cream does not affect the ability to drive or use machines or only has a negligible effect.

Important information about some of the medicine ingredients:

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

3) How will you use the medicine?

You should 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 your doctor, follow any instructions he/she 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:

Treatment 2 to 3 times a day.

Taking the medicine:

- 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 0.5 cm will be enough to treat a palm-sized area.
- The duration of treatment of fungal skin infections depends on the type of infection. For the most part, 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 doctor 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 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 swallowed the preparation, you should contact your doctor immediately or go to the emergency room at the nearest hospital.
- Avoid contact of the preparation with the eyes or mouth. In case of contact with the eyes, rinse well with water and consult a doctor.
- **If you have accidentally taken a higher dosage**, if you took an overdose or a child swallowed the medicine by mistake, go immediately to the doctor or to the emergency room of a hospital and take the medicine package with you.
- **If you forget to apply the preparation on time**
 - o Apply immediately as soon as you have remembered and continue the rest of the treatment as usual.
- **How can you assist in treatment success?**
 - o Although the affected area is itchy, avoid scratching the area. Scratching may cause damage to the skin surface and thus spread the infection.
 - o Keep infected areas clean.
 - o Dry the area thoroughly but avoid excessive rubbing.
 - o Do not share towels, bath mat etc. with other people as they may get the infection.
 - o Always wash your hands after treating the infection to prevent its spread.
- If you suffer from athlete's foot:
 - o Be sure to dry the skin between the toes thoroughly.
 - o Wash your socks and stockings/tights thoroughly in hot water to remove any shed skin or fungal spores.
 - o 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 doctor or pharmacist.

4) Side effects:

Like all medicines, the use of Canesten® 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 your doctor immediately or go to an emergency room at the closest 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 one of the following symptoms: Itching, rash, blisters, burning, discomfort, swelling, irritation, redness or peeling of the skin.

If you experience any side effect, if any side effect worsens, or if you suffer from a side effect not mentioned in the leaflet, you should consult the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting of side effects due to a medicinal treatment" found on the homepage of the Ministry of Health website (www.health.gov.il), which links to the online form for reporting on side effects, or by clicking on the link:

<https://sideeffects.health.gov.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 in order to avoid poisoning. Do not induce vomiting without an explicit instruction from 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.
- Storage conditions:
 - o Store under 30°C.
 - o Do not use more than 3 months after opening.

6) Additional Information

- In addition to the active ingredient, the medicine also contains excipients: Purified water, octyldodecanol, cetostearyl alcohol, cetyl palmitate, benzyl alcohol, sorbitan stearate, polysorbate 60. See section "Special warnings regarding the use of the medicine" with regard to cetostearyl alcohol.
- What does Canesten® cream look like?
Canesten® cream is a white cream, packed in a 20 or 30 gram tube. Not all pack sizes may be marketed.
- Name and address of the Marketing Authorisation Holder: Bayer Israel Ltd., 36 Hacharash St., Hod Hasharon 45240.
- Name and address of the manufacturer: Kern Pharma S.L., Barcelona, Spain.
- This leaflet was reviewed and approved by the Ministry of Health on January 2018 and was updated according to the guidelines of the Ministry of Health in November 2019.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 149-44-33680-00.