



Canesten®

Package leaflet: information for the user

Canesten® Cream

1% cream

Active substance: Clotrimazole

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- ▶ Keep this leaflet. You may need to read it again.
- ▶ Ask your pharmacist if you need more information or advice.
- ▶ If you notice any side effects not listed in this leaflet, please consult your doctor or pharmacist

What is in this leaflet

1. What Canesten is and what it is used for
2. What you need to know before you use Canesten
3. How to use Canesten
4. Possible side effects
5. How to store Canesten
6. Contents of the pack and other information

1. WHAT CANESTEN IS AND WHAT IT IS USED FOR

Canesten Cream contains the active substance clotrimazole. This active substance destroys fungi that infect human skin and lead to superficial fungal diseases (mycoses). It also acts against certain bacteria on the skin. Canesten Cream can also be used for nappy rash and fungal infections on the glans and penis.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE CANESTEN

When not to use Canesten

You should not use Canesten Cream if you are hypersensitive to other anti-fungal products (imidazole-type antimycotics) or to any other ingredient in the product.

In known cases of hypersensitivity to cetostearyl alcohol, it is advisable to use a form containing no cetostearyl alcohol, instead of the cream.

Canesten Cream should not be used on the oral or nasal mucosa, in or on the eyes, or swallowed.

Warnings and precautions:

Consult a doctor if the fungal infection is extensive or if your nails are also affected.

Special forms of Canesten are available for the treatment of fungal infections of the female genitals.

Canesten Cream can reduce the tear resistance and thus the safety of latex products such as condoms or diaphragms when applied to the genital area (women: labia and surrounding skin; men: glans and foreskin). This effect is temporary and limited to the time of treatment.

If taking tacrolimus concurrently, you should consult your doctor before applying Canesten Cream to the glans or foreskin as any potential tacrolimus overdose must be carefully monitored.

Inform your doctor or pharmacist if you:

- suffer from any other illnesses
- have allergies or
- are taking or externally applying any other medicines (including those you purchase yourself).

Pregnancy and breastfeeding

Canesten should not be used during pregnancy or when breastfeeding unless prescribed by a doctor.

As a precaution, you should avoid taking medications during pregnancy and while breastfeeding if possible, or you should ask your doctor or pharmacist for advice.

3. HOW TO USE CANESTEN

Adults and children over 2 years

Unless otherwise prescribed, apply Canesten Cream thinly to the affected areas 2–3 times daily and rub in gently. To treat fungal infections of the ear canal where the eardrum is intact, coat a gauze strip with Canesten Cream and place it in the ear canal as a loose tamponade.

To treat nappy rash with Canesten Cream, apply the cream thinly to the affected areas 2–3 times daily. The treatment should be continued for at least 7 days. A doctor should then assess the success of the treatment and decide if treatment should be continued.

Children under 2 years

Canesten Cream should be used in children under 2 years of age only if prescribed by a doctor.

For successful treatment it is important to use Canesten Cream **reliably and for a sufficient period** (see below). Treatment duration varies depending on the extent and location of the affected area.

For fungal infections of the skin it is usually 3–4 weeks.

In the case of athlete's foot, treatment should be continued for approximately 2 weeks after all signs of infection have disappeared – even if improvement is rapid – to prevent recurrences.

To prevent the fungal infection from recurring, be sure to dry the affected areas of the body thoroughly after washing. It is particularly important to dry between the fingers and toes.

Consult your doctor if the symptoms worsen or if no improvement is seen after four weeks.

For fungal infections of the glans and foreskin, treatment lasting 1 - 2 weeks is generally sufficient.

4. POSSIBLE SIDE EFFECTS

The following side effects can occur when using Canesten Cream:

Hypersensitivity and skin reactions can occur, such as dry skin, burning sensation, blistering, swelling, stinging, reddening of the skin, itching, scaling, urticaria, shortness of breath, loss of blood pressure up to fainting.

Skin reactions can be caused by pre-existing hypersensitivity to cetostearyl alcohol or another ingredient in the product.

Systemic effects are not to be expected after external application.

You should also inform your doctor or pharmacist if you notice any side effects that are not described here.

5. HOW TO STORE CANESTEN

Not to be stored above 25°C.

The product may only be used up to the date marked "EXP" on the container.

Keep out of reach of children.

You can obtain further information from your doctor or pharmacist. These persons have the complete information for professionals.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Canesten contains

Canesten Cream (oil-water emulsion):

Active substance: 1 g Canesten Cream contains 10 mg clotrimazole.

Excipients: benzyl alcohol, cetyl palmitate, cetostearyl alcohol, purified water, octyldodecanol, Polysorbate 60, Sorbitan stearate.

Always use the dosage described in this leaflet or as prescribed by your doctor. If you think that the effect of the medicine is too weak or too strong, speak to your doctor or pharmacist.

Where Canesten can be obtained What pack sizes are available?

Available in pharmacies without prescription.

Cream available in tubes containing 20 g

Manufactured by Kern Pharma, S.L., Spain for Bayer Consumer Care AG – Basel – Switzerland.

This package leaflet was last reviewed in October, 2014.

This is a medicament

- ▶ A medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- ▶ Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- ▶ The doctor and the pharmacist are experts in medicine, its benefits and risks.
- ▶ Do not by yourself interrupt the period of treatment prescribed.
- ▶ Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children.

Council of Arab Health Ministers

Union of Arab Pharmacists