

Patient leaflet: Information for the user

Canesten® 10 mg/g Cream

clotrimazole

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

Always use this medicine exactly as described in this leaflet or as your pharmacist has told you. Keep this leaflet. You may need to read it again.

- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must contact a doctor if your symptoms worsen or do not improve.

What is in this leaflet

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1. What is Canesten Cream and what it is used for

Canesten Cream is used to treat fungal skin infections such as ringworm, athlete's foot, fungal nappy rash and fungal sweat rash. It is also used to relieve irritation of the vulva (external thrush) or the end of the penis, which may be associated with thrush.

If you are unsure whether you (or your baby if treating nappy rash) have one of these fungal skin infections, seek the advice of your doctor or pharmacist.

The active substance in Canesten Cream is clotrimazole. Clotrimazole belongs to a group of medicines called imidazoles and is an antifungal agent which fights the cause of fungal skin infections.

2. What you need to know before you use Canesten Cream

Do not use Canesten Cream

If you (or your baby if treating nappy rash) are allergic (hypersensitive) to clotrimazole or any of the other ingredients including cetostearyl alcohol or benzyl alcohol, of Canesten Cream (listed in section 6).

Canesten Cream contains cetostearyl alcohol and benzyl alcohol.

This product contains cetostearyl alcohol which may cause local skin irritation (e.g. rash, itching or redness). This product contains 20mg benzyl alcohol in each gram of cream. Benzyl alcohol may cause allergic reactions. Benzyl alcohol may cause mild local irritation..

As with other creams, Canesten Cream may reduce the effectiveness of rubber contraceptives, such as condoms or diaphragms. Consequently, if you are using this cream on the vulva or penis, you should use alternative precautions for at least five days after using this product.

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine. Canesten Cream can be used in pregnancy and breastfeeding, but only under the supervision of your doctor or midwife. You must follow his/her instructions for use. If you are applying this medicine to the nipple area, wash the area well before breastfeeding.

3. How to use Canesten Cream

- Always use this medicine exactly as described in this leaflet or as your pharmacist has told you. Check with your pharmacist if you are not sure: Before use, pierce the tube seal by inverting the cap over the end of the tube and press.

- If the feet are infected, they should be washed and dried thoroughly, especially between the toes before applying the cream.
- Canesten Cream should be applied thinly and evenly to the affected areas two or three times daily and rubbed in gently.
- The duration of the treatment depends upon the type of infection. Generally a minimum of two weeks is required, although up to four weeks may be necessary.
- If you have athlete's foot, it may help to use an antifungal dusting powder as well. Ask your doctor or pharmacist to recommend one.

The symptoms of skin infection, such as itching or soreness, should improve within a few days of treatment although signs such as redness and scaling may take longer to disappear. If no improvement is seen after four weeks, you must tell your doctor.

Canesten Cream is for external use only:

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

If the cream is swallowed accidentally, tell your doctor straight away or contact the Accident and Emergency Department of your nearest hospital.

Avoid contact with the eyes. If you accidentally get cream in your eyes or mouth, wash immediately with water and contact your doctor.

If you forget to use Canesten Cream:

Apply the cream as soon as possible and then continue the rest of your treatment as usual.

You can help the treatment to work if you follow these simple self-help tips:

- Although the infected area will itch, try not to scratch. Scratching will damage the surface of the skin and cause the infection to spread further.
- Keep the affected skin areas clean.
- Pay particular attention to drying the skin, but avoid excessive rubbing.
- Do not share towels, bath mats, etc. with other people as you could spread the infection to them.
- Always wash your hands after treating the infection to prevent it from spreading.

If you have athlete's foot:

- Remember to dry the skin between the toes thoroughly.
- Wash your socks, stockings, and tights thoroughly in hot water to remove any shed skin or fungal spores.
- Change your footwear daily if possible.

4. Possible side effects

Like all medicines, Canesten Cream can cause side effects, although not everybody gets them.

As with all medicines, some people may be allergic to the cream. If you or your baby are allergic, a reaction will occur soon after you start using it. If you or your baby experience an allergic reaction, stop using Canesten Antifungal Cream and tell your doctor straight away or contact the Accident and Emergency Department of your nearest hospital. Signs of an allergic reaction may include:

- Rash
- Swallowing or breathing problems
- Swelling of your lips, face, throat or tongue.
- Weakness, feeling dizzy or faint.
- Nausea.
- Low blood pressure.

After you apply the cream, you might experience:

Irritation, burning, pain, discomfort, itching, redness, rash, swelling, blisters, peeling of skin, pins and needles.

If you experience any of the above effects, tell your doctor or pharmacist immediately.

Reporting of side effects

If you or your baby gets any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC Pharmacovigilance, Website: www.hpra.ie. By reporting

side effects you can help provide more information on the safety of this medicine.

5. How to store Canesten Cream

Keep this medicine out of the sight and reach of children.

Do not store above 25 °C.

Do not use Canesten Cream after the expiry date which is stated on the carton and tube after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Canesten Cream contains:

- The active substance is clotrimazole. Each gram of cream contains 10 mg clotrimazole equivalent to 1% w/w.
- The other ingredients are benzyl alcohol, polysorbate 60, sorbitan stearate, cetyl palmitate, cetostearyl alcohol, 2-octyldodecanol and purified water.

See Section 2 'Important information about some of the ingredients' for benzyl alcohol and cetostearyl alcohol advice.

What Canesten Cream looks like and contents of the pack:

Canesten Cream is available in tubes containing 20 g of white cream.

Product procured from within the EU, repackaged and distributed by the Parallel Product Authorisation Holder:

PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

Parallel Product Authorisation Number: PPA 465/48/1

Manufacturer

Bayer AG, Leverkusen, Germany or FAMAR A.B.E., Avlonas, Athens, Greece or Kern Pharma S.L/ Kern Pharma S.A., Terrassa, Spain or GP Grenzach Produktions GmbH, Germany

Remember: If you have any doubts about using Canesten Cream correctly, seek the advice of your doctor or pharmacist.

Further information about fungal infections:

Fungal infections are very common and affect many people. Some of the most common fungal skin infections include athlete's foot, nappy rash, sweat rash and ringworm.

There are two main types of fungal infection:

- The tinea group, also known as dermatophytes.
- The candida group, also known as yeasts.

The tinea group includes athlete's foot and ringworm, both of which are easily spread by contact. The fungus that causes athlete's foot usually lives harmlessly on our skin and in our environment. The natural balance that normally keeps it under control can be upset by factors such as damp moist conditions. This could happen, for example, through regularly wearing training shoes that keep the feet hot and sweaty. Since this fungus is contagious, it can also often be picked up in changing rooms. Ringworm is usually passed on from animals to children. Ringworm is not actually a worm, its name comes from the circular worm-like shape that it forms on the skin. The main symptom for both is an itchy, scaly and irritating rash.

The candida group can be responsible for conditions such as sweat rash and thrush. Sweat rash can appear anywhere on the body, but is more likely to occur where folds of skin rub against each other, such as: under the breasts, under arms, around the groin and on the back. Candida is a yeast-like fungus that usually lives harmlessly on our skin. However, the natural balance that normally keeps it under control can be upset by factors such as sweating, tight or synthetic clothing and cosmetic preparations such as bath additives. When levels of the yeast increase, the skin can develop the following symptoms: persistent burning and itching, soreness and a variety of patches or blemishes as well as a softened and soggy appearance.

The candida group can also be responsible for nappy rash. Most babies develop nappy rash at some stage. Although this is rarely a serious condition, the rash can be extremely distressing for both you and your baby. Nappy rash which lasts longer than three days may be fungal in origin and will require an antifungal treatment. The symptoms of fungal nappy rash include red patches on the baby's bottom and genitals, burning and itching.

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