

Canesten® Cream

(clotrimazole 1% w/w)

Patient Information Leaflet

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to use Canesten Cream carefully to get the best results from it.

- * Keep this leaflet. You may need to read it again.
- * Ask your pharmacist if you need more information or advice.
- * You must contact a doctor if your symptoms worsen or do not improve.
- * If you have any unusual effects after using this product, tell your doctor or pharmacist.

In this leaflet

- 1 What is Canesten Cream and what is it used for?
- 2 Before you use Canesten Cream
- 3 How to use Canesten Cream
- 4 Possible side effects
- 5 How to store Canesten Cream
- 6 Further information

1 What is Canesten Cream and what is it 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 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 of Canesten Cream.

Important information about some of the ingredients:

This product contains cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis).

Special precautions:

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 and breast-feeding:

Avoid using this medicine during the first trimester of pregnancy. If you are pregnant, breast-feeding or trying for a baby, tell your doctor or midwife before using Canesten Cream. Breast-feeding should be discontinued during treatment with this medicine.

3 How to use Canesten Cream

If Canesten Cream 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, follow these directions closely:

- * 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 anitfungal 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

Canesten® Cream

(clotrimazole 1.0% w/w)

Patient Information Leaflet (continued)

Rarely, immediately after you apply the cream you or your baby might experience the following symptoms:

- * Mild burning.
- * Irritation.

If this is intolerable, stop treatment and see your doctor as soon as possible.

Very rarely, Canesten Antifungal Cream may cause side effects which can be very similar to the symptoms of the infection. If any of these symptoms get worse, stop treatment and see your doctor as soon as possible.

These symptoms may include

- * Burning, pain or itching.
- * Redness
- * Rash
- * Swelling

Other potential side effects have been reported:

Peeling skin, blisters, low blood pressure.

Reporting of side effects

If you or your baby get 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@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 out of the sight and reach of children.

This product should be stored in the original carton.
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.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 Further information

What Canesten Cream contains:

- * The active substance is clotrimazole, at a strength of 1% w/w.
 - * The other ingredients are benzyl alcohol, polysorbate 60, sorbitan stearate, cetyl palmitate cetostearyl alcohol, octyldodecanol and purified water.
- See Section 2 ‘ Important information about some of the ingredients’ for cetostearyl alcohol advice.**

What Canesten Cream looks like and contents of the pack:

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

The Parallel Product Authorisation Holder is:

LTT Pharma Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.

Repackaged by:

Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.

The manufacturer is:

Kern Pharma S.L., Poligon Industrial Colon II, Calle Venus 72, 08228 Terrassa, Barcelona, Spain.

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.

Canesten is a registered trademark of Bayer AG.

Revision date: 28/09/2015

P PPA1562/191/001

Blind or partially sighted?

Is this leaflet hard to see or read?

Phone LTT Pharma Limited,

Tel: +44 (0)1527 505414 for help.