

PACKAGE LEAFLET: INFORMATION FOR THE USER

Canesten HC Cream Clotrimazole 1.0% w/w Hydrocortisone 1.0% w/w

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

Keep this leaflet. You may need to read it again.

- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not give it to anyone else under any circumstances.
- If you have any unusual effects after using this product, tell your doctor.

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1. WHAT IS CANESTEN® HC CREAM AND WHAT IS IT USED FOR?

Canesten HC Cream is used to treat fungal skin infections when there are additional symptoms of inflammation (such as swelling, redness and itching). Canesten HC treats the fungal skin infection and reduces the swelling and itching caused by it.

Canesten HC Cream is used for the treatment of infection and irritation of the vulva or end of the penis (glans) caused by thrush. It is also used to treat nappy rash and fungal infection of the breast fold (intertrigo), as well as infections such as ringworm and athlete's foot.

The active substances in Canesten HC Cream are clotrimazole and hydrocortisone. Clotrimazole belongs to a group of medicines called imidazoles, which destroy the fungi and some bacteria that cause skin infections. Hydrocortisone is a mild steroid which reduces swelling, redness and itching associated with inflammation of the skin.

2. BEFORE YOU USE CANESTEN® HC CREAM

Do not use Canesten® HC Cream:

- If you (or your baby if treating nappy rash) are allergic (hypersensitive) to clotrimazole, hydrocortisone or any of the other ingredients of Canesten HC Cream.
- On areas of broken skin.
- On large areas of skin (more than 5–10% of body surface).
- For longer than 7 days.
- To treat cold sores or acne.
- On your face, eyes, mouth or around it.
- On any untreated bacterial skin infection, such as syphilis or tuberculosis.
- On vaccination reactions.
- On shingles, chicken pox, rosacea or herpes.

If you are unsure about any of these restrictions, speak to your doctor.

Important information about some of the ingredients:

This product contains cetostearyl alcohol which may cause local skin irritation (e.g. rash, itching or redness).

Special precautions:

- As with all steroids, long-term, continuous use on large areas of skin should be avoided, particularly in infants and children.
- Do not cover the area being treated with a dressing or bandage.
- In infants, care should be taken not to fasten nappies too tightly over the treated area, as this may increase the absorption of the hydrocortisone.
- Wash your hands immediately after applying the cream.
- As with other creams, this product 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 product 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 HC Cream. Breast-feeding should be discontinued during treatment with this medicine.

3. HOW TO USE CANESTEN® HC CREAM

Unless directed otherwise by your doctor, 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 HC Cream should be applied thinly and evenly to the affected areas twice daily and rubbed in gently. Approximately 1cm of cream per application should be enough.
- Do not cover the area being treated with a dressing or bandage.
- As with all products containing hydrocortisone, you should wash your hands immediately after applying the cream.

Treatment should be continued for no more than 7 days.

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 the symptoms persist or you do not start to improve after 7 days, consult your doctor.

Canesten® HC 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.

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

If you forget to use Canesten® HC 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 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 HC 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 HC 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.

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.

Other potential skin reactions that have been reported:

- Discomfort/pain
- Itching
- Redness
- Broken veins

- Excess hair growth
- Stretch marks
- Thinning or whitening of skin
- Secondary infections
- An acne-like rash

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 HPRAs 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® HC CREAM

Keep out of the reach and sight of children.

This product should be stored in the original carton.

Do not store above 25°C.

Do not use Canesten HC Cream after the expiry date which is stated at one end of the carton and on the end of the tube of cream. 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® HC Cream contains:

- The active substances are clotrimazole and hydrocortisone, each at a strength of 1% w/w.
- The other ingredients are benzyl alcohol, cetostearyl alcohol, tricetareth-4-phosphate, medium chain triglycerides and purified water.

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

What Canesten® HC Cream looks like and contents of the pack:

Canesten HC Cream is available in tubes containing 30g of white to pale yellow cream.

Parallel Product Authorisation Holder and Manufacturer

Product procured from within the EU by the Parallel Product

Authorisation Holder:

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue,
Northwest Business Park
Ballycoolin, Dublin 15
Ireland

Manufacturer:

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

Repackaged by:

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue,
Northwest Business Park
Ballycoolin, Dublin 15
Ireland

Remember: This medicine has been prescribed for you. Do not give it to anyone else under any circumstances. If you have any doubts about using Canesten® HC 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, ringworm and thrush.

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.

This leaflet was last approved in March 2018

Canesten is a registered trademark of Bayer AG, Germany.