

Clotrimazole Hydrocortisone acetate Leaflet may vary from the one found in your medicine pack. Please compare the 'Leaflet prepared/revised date' towards the end of the leaflet to establish if there have been any changes

If you have any doubts or queries about your medication, please contact your doctor or pharmacist.

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.

IN THIS LEAFLET

- 1. What is Canesten HC Cream and what is it used for?
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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 acetate. Clotrimazole belongs to a group of medicines called imidazoles, which destroy the fungi and some bacteria that cause skin infections. Hydrocortisone acetate 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, including cetostearyl alcohol, 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 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.

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 acetate. 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.
- Contact your doctor if you experience blurred vision or other visual disturbances.

Pregnancy and breast-feeding:

If you are pregnant, breast-feeding or trying for a baby, tell your doctor or midwife before using Camesten HC Cream. If you have informed your doctor or midwife already, follow his/her instructions carefully.

Important information about some of the ingredients:

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

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.

Due to regulatory changes, the content of the following Patient Information

Bayer HealthCare

You can help the treatment to work if you follow these 6. FURTHER INFORMATION simple self-help tips: What Canesten® HC Cream contains

- 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.
- After you apply the cream you might experience:
- Itching, rash, blisters, burning, discomfort, swelling, irritation, redness or peeling of skin, blurred vision.

Treatment should be limited to 7 days unless advised otherwise This could happen, for example, through regularly wearing by your doctor. If you apply the cream to a large area or under training shoes that keep the feet hot and sweaty. Since this a dressing, or if you use the cream for more than 2 weeks, you may experience skin reactions such as:

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

If you or your baby experience any of the above effects or react badly to the cream in any other way not listed in this leaflet, tell vour doctor immediately.

Reporting of side effects

If you 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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. 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 sight and reach of children.

This product should be stored in the original carton. Do not store above 25°C.

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 after "Sen". The state of the state of the tube of tube tube tube of "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 Bayer AG, Germany. required. These measures will help to protect the environment.

- The active substances are clotrimazole and hydrocortisone acetate. Fach gram of cream contains 10mg clotrimazole and 11.2mg hydrocortisone acetate (equivalent to 10mg hvdrocortisone)
- The other ingredients are benzyl alcohol, cetostearyl alcohol, triceteareth-4-phosphate, medium chain triglycerides, purified water, sodium hydroxide and hydrochloric acid. See Section 2 ' Do not use' and ' Important information about some of the inaredients' for cetostearvl alcohol advice.

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

Canesten HC Cream is available in tubes containing 5g or 30g of white cream. Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Bayer plc, 400 South Oak Way, Reading, RG2 6AD, UK Manufacturer:

Kern Pharma S.L.

Poligon Industrial Colon II, Calle Venus 72 08228 Terrassa, Barcelona, Spain 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 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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