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Canesten[®]

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 or pharmacist.

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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 Cream 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 or benzyl 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.

Cream

HC

Clotrimazole & Hvdrocortisone acetate

Warnings and precautions:

Talk to your doctor or pharmacist or nurse before using Canesten HC Cream.

- 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.
- Do not smoke or go near naked flames risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

Pregnancy and breastfeeding: If you are pregnant, breastfeeding or trying for a baby, tell your doctor or midwife before using Canesten 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 reactions (e.g. contact dermatitis). The medicine also contains 20mg benzyl alcohol in each gram of cream. Benzyl alcohol may cause allergic reactions and mild local irritation.

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 feet are infected; before applying the cream, they should be washed and dried thoroughly, especially between the toes.
- 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 sufficient.
- 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 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 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, including between the toes, 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 the

following symptoms:
Itching, rash, blisters, burning, discomfort, swelling, irritation, redness or peeling of skin, blurred vision.

Treatment should be limited to 7 days unless advised otherwise by your doctor. If you apply the cream to a large area or under 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 your 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 or search for MHRA Yellow Card in the Google Play or Apple App Store. 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. Once opened, use within 6 months.

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 acetate. Each gram of cream contains 10mg clotrimazole and 11.2mg hydrocortisone acetate (equivalent to 10mg hydrocortisone).
- 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 ingredients' for cetostearyl and benzyl 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:

GP Grenzach Produktions GmbH, 79639 Grenzach-Whylen, Germany

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.

For UK residents only: If you have any further questions you can call us on 0118 206 3232.

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