

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



Canesten®

Hydrocortisone

Clotrimazole 1% w/w
Hydrocortisone 1% w/w



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 Hydrocortisone 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 after 7 days.
- If you have any unusual effects after using this product, tell your doctor or pharmacist.

IN THIS LEAFLET

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

1. WHAT IS CANESTEN® HYDROCORTISONE AND WHAT IS IT USED FOR?

Canesten Hydrocortisone is used to treat athlete's foot and fungal sweat rash when there are additional symptoms of inflammation (such as swelling, redness and itching).

Canesten Hydrocortisone treats the fungal skin infection and reduces the swelling and itching caused by it.

If you are unsure whether you have one of these fungal skin infections, seek the advice of your doctor or pharmacist.

The active substances in Canesten Hydrocortisone 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® HYDROCORTISONE

Do not use Canesten® Hydrocortisone:

- If you have a fungal infection without specific symptoms of inflammation, an antifungal medicine without hydrocortisone may be more appropriate.
- If you are allergic (hypersensitive) to clotrimazole, hydrocortisone or any of the other ingredients, including cetostearyl alcohol, of Canesten Hydrocortisone.
- 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 mucous membranes.
- 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 or pharmacist.

Unless prescribed by a doctor, you should not use Canesten Hydrocortisone:

- If pregnant or breast-feeding.
- In children under 10 years.
- In the vagina or on the vulva.
- On the penis or scrotum.
- Around the anus.
- To treat ringworm.
- On areas of skin affected by eczema, psoriasis or dermatitis.

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

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.
- Do not cover the area being treated with a dressing or bandage.
- Wash your hands immediately after applying the cream.

Pregnancy and breast-feeding:

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

3. HOW TO USE CANESTEN® HYDROCORTISONE

If Canesten Hydrocortisone 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 Hydrocortisone 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 do not start to improve after 7 days, consult your doctor.

Canesten® Hydrocortisone 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® Hydrocortisone:

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 Hydrocortisone can cause side effects, although not everybody gets them.

As with all medicines, some people may be allergic to the cream. If you are allergic, a reaction will occur soon after you start using it. If you experience an allergic reaction, stop using Canesten Hydrocortisone 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 or peeling of skin.

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

5. HOW TO STORE CANESTEN® HYDROCORTISONE

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 Hydrocortisone 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® Hydrocortisone 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 'Do not use' and 'Important information about some of the ingredients' for cetostearyl alcohol advice.

What Canesten® Hydrocortisone looks like and contents of the pack:

Canesten Hydrocortisone is available in tubes containing 15g of white cream.

Marketing Authorisation Holder:

Bayer plc, Consumer Care Division, Bayer House, Strawberry Hill, Newbury, Berkshire RG14 1JA, UK

Manufacturer:

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

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

Further information about fungal infections:

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

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 which is 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. The main symptom is an itchy, scaly and irritating rash.

The candida group can be responsible for conditions such as sweat rash. 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.

For UK residents only: if you have any questions or would like more information, call our Canesten Advice Line on 0845 758 5030. Calls charged at local rate.

This leaflet was last approved in December 2009.

Canesten is a registered trademark of Bayer AG, Germany.

Bayer