

Canesten®



Bifonazole Once Daily 1% w/w Cream

Bifonazole

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 Bifonazole Once Daily 1% w/w 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 or pharmacist if your symptoms worsen or do not improve within 7 days.
- If you have any unusual effects after using this product, tell your doctor or pharmacist.

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

Canesten Bifonazole Once Daily 1% w/w Cream is used to treat athlete's foot.

If you are unsure whether you have athlete's foot, seek the advice of your doctor or pharmacist.

The active substance in Canesten Bifonazole Once Daily 1% w/w Cream is bifonazole. Bifonazole 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® BIFONAZOLE CREAM

Do not use Canesten® Bifonazole Once Daily 1% w/w Cream:

- If you are allergic (hypersensitive) to bifonazole or any of the other ingredients of Canesten Bifonazole Once Daily 1% w/w Cream (see section 6, Further Information).
- To treat nappy rash. If your baby has nappy rash, seek your doctor's advice for a suitable treatment.
- To treat nail and scalp infections.
- To treat vaginal infections.

Before using Canesten® Bifonazole Once Daily 1% w/w Cream, you should seek the advice of your doctor or pharmacist if:

- you are unsure whether you have athlete's foot.
- you have ever had an allergic reaction to any antifungal product.

Important information about some of the ingredients:

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

Using other medicines:

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, especially warfarin (an anticoagulant used to prevent blood clots).

Pregnancy and breast-feeding:

Do not use Canesten Bifonazole Once Daily 1% w/w Cream if you are pregnant or breast-feeding, unless on the advice of your doctor.

3. HOW TO USE CANESTEN® BIFONAZOLE CREAM

If Canesten Bifonazole 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.
- Before applying the cream, your feet should be washed and dried thoroughly, especially between the toes.
- The cream should be applied thinly and evenly to the affected areas once daily, preferably at night before going to bed, and rubbed in gently.
- Treatment should be continued for 2-3 weeks.
- It may help to use an antifungal dusting powder as well. Ask your doctor or pharmacist to recommend one.

The symptoms of athlete's foot, 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 symptoms do not improve within 7 days, consult your doctor or pharmacist.

Canesten® Bifonazole 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® Bifonazole 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.
- 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 Bifonazole Once Daily 1% w/w Cream 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 Bifonazole 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:

- Slight irritation or burning.
- Reddening of the skin.
- Peeling.

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

Canesten Bifonazole Cream may cause a local skin irritation which can be very similar to the symptoms of the infection. If any of your symptoms gets worse, stop treatment and see your doctor as soon as possible.

These symptoms may include:

- Burning, pain or itching.
- Rash, redness, dryness.
- Soft or soggy appearance to the skin.
- Swelling, hives, blisters.

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® BIFONAZOLE CREAM

Keep out of the reach and sight of children.

This product should be stored in the original carton.

Do not use Canesten Bifonazole 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® Bifonazole Once Daily 1% w/w Cream contains:

- The active substance is bifonazole at a strength of 1% w/w
- The other ingredients are sorbitan stearate, polysorbate 60, cetyl palmitate, cetostearyl alcohol, 2-octyldodecanol, benzyl alcohol and purified water.

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

What Canesten® Bifonazole Once Daily 1% w/w Cream looks like and contents of the pack:

Canesten Bifonazole Once Daily 1% w/w Cream is available in tubes containing 15g, 20g, 25g and 30g of white cream. Not all pack sizes may be marketed.

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 Bifonazole Once Daily 1% w/w Cream correctly, seek the advice of your doctor or pharmacist

Further information about fungal infections:

Fungal infections are very common and affect many people. One of the most common fungal skin infections is athlete's foot (Tinea pedis). It is caused by a contagious fungus which thrives in warm, moist environments. 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.

Tell-tale signs of athlete's foot are that the skin becomes itchy, red and inflamed. Sporty people or those who work in a warm, damp environment, tend to be more likely to catch this condition.

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.