

PACKAGE LEAFLET: INFORMATION FOR THE USER

CANESPOR

Cream

BIFONAZOLE 1% W/W

• *This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine 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 only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •*

What is in this leaflet?

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1. WHAT IS CANESPOR CREAM AND WHAT IS IT USED FOR?

Canespor Cream is used to treat fungal skin infections such as ringworm, athlete's foot and fungal sweat rash. The active substance in Canespor 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 CANESPOR CREAM

Do not use Canespor Cream:

- If you are allergic (hypersensitive) to bifonazole or any of the other ingredients of Canespor Cream.
- To treat nappy rash. If your baby has nappy rash, seek your doctor's advice for a suitable treatment.

Before using Canespor Cream, see your doctor if:

- 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).

Pregnancy and breast-feeding:

Do not use Canespor Cream if you are pregnant or breast-feeding.

3. HOW TO USE CANESPOR 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.
- Before applying the cream, the infected skin should be washed and dried thoroughly, especially between the toes if the feet are infected.
- 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, depending on the type of infection.
- If you have athlete's foot, it may help to use an antifungal dusting powder as well. Ask your doctor or pharmacist to recommend one.

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 symptoms persist, consult your doctor.

Canespor 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 Canespor 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, 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, Canespor 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 Canespor 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.

Canespor 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.
- Redness.
- Rash.
- Swelling.

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 immediately.

5. HOW TO STORE CANESPOR CREAM

Keep out of the reach and sight of children.

This product should be stored in the original carton.

Do not use Canespor 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.

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 Canespor 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, ringworm 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 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. 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.

This leaflet was last revised in August 2008.