

Package leaflet: Information for the user

Canespor 10mg/g Cream

Bifonazole

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet

1. What Canespor Cream is and what it is used for
2. What you need to know before you use Canespor Cream
3. How to use Canespor Cream
4. Possible side effects
5. How to store Canespor Cream
6. Contents of the pack and other information

1. What Canespor Cream is and what it is used for

Canespor Cream contains bifonazole. Bifonazole belongs to a group of medicines called imidazoles. It penetrates into the affected skin layers, where it kills the fungi.

Canespor Cream is used in adults to treat **fungal skin infections** of the:

- **feet or between the toes** (Athlete's Foot)
- **nail bed** after removal of the infected nail using topical treatment such as urea ointment

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

2. What you need to know before you use Canespor Cream

Do not use Canespor Cream

- if you are allergic to bifonazole or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using Canespor Cream if you have

- had an allergic reaction to any other medicine to treat fungal infections such as econazole, clotrimazole, miconazole
- diabetes

Nail bed treatment with Canespor Cream requires that you firstly **remove** the infected **nail using a local treatment**, such as urea ointment.

Please note:

- Use with care on broken or raw skin.
- Do not cover the area with a bandage after you have applied Canespor Cream.
- Avoid getting Canespor Cream in the eyes.
- Do not swallow the medicine.

Children and adolescents

Canespor Cream should only be used on infants and children if it is prescribed for them by a doctor. Please ensure that no cream finds its way into the infant's mouth.

Other medicines and Canespor Cream

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Patients who are taking **warfarin** to prevent or treat clots must have their warfarin blood test monitored carefully by a doctor while using Canespor Cream.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

- **Pregnancy**
Canespor Cream is not recommended to be used during pregnancy or in women who might conceive unless appropriate contraception measures are taken.
- **Breast-feeding**
Discontinue breast-feeding while using Canespor Cream.

Driving and using machines

Canespor Cream has no influence on the ability to drive and use machines.

Canespor Cream contains cetostearyl alcohol and benzyl alcohol.

Cetostearyl alcohol may cause local skin irritation (e.g. contact dermatitis). Benzyl alcohol may cause mild local irritation.

3. How to use Canespor Cream

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Before each use wash the affected skin areas to remove loose flakes of skin and any residue from the previous treatment. After washing, dry the areas thoroughly, especially hard-to-reach areas such as between the toes.

The recommended dose is

Once Daily, approximately 1 cm squeezed from the tube is usually sufficient for an area about the size of the palm.

Method of use

Apply a thin layer of Canespor Cream and gently rub into the affected skin areas, ideally in the evening before bed. Wash your hands after use.

Change your towels and any clothing that comes into contact with the affected areas daily.

This prevents the fungal infection from being transmitted to other parts of the body or other people.

Duration of use

To achieve long-term successful results, continue applying Canespor Cream for the duration shown below, even if symptoms have cleared.

Recommended duration of treatments for fungal infections of the:

feet or between the toes (Athlete's Foot)	3 weeks
nail bed after removal of the infected nail	4 weeks

You must talk to a doctor if you do not feel better or if you feel worse.

If you feel that the effects of Canespor Cream are too strong or too weak, please talk to your doctor or pharmacist.

If you use more Canespor Cream than you should

If you apply too much Canespor Cream or if you swallow it, contact your doctor or pharmacist.

If you forget to use Canespor Cream

Continue the treatment in accordance with the recommendation of your doctor or pharmacist or as described in this package leaflet.

Do not use a double dose to make up for a forgotten dose.

If you stop using Canespor Cream

If you interrupt the treatment with Canespor Cream or end it too soon, the infection may not be fully cleared and may come back again.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very common: may affect more than 1 in 10 people

- burning skin/burning sensation

Uncommon: may affect up to 1 in 100 people

- localized swelling
- redness, eczema, skin irritation and itching

Not known: frequency cannot be estimated from the available data

- pain at the site of administration
- allergic skin reactions and rashes
- hives, fluid-filled bumps on the skin, peeling of the skin
- dry skin, softening of the skin

The above side effects usually go away once treatment is stopped.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine

5. How to store Canespor Cream

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the tube label and the carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Once opened, use within 16 months but not beyond the expiry date.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other

information What Canespor Cream contains

- The active substance is bifonazole
- 1 g of cream contains 10 mg bifonazole.
- The other ingredients are benzyl alcohol, cetostearyl alcohol, cetyl palmitate, octyldodecanol, polysorbate 60, purified water, sorbitan stearate.

What Canespor Cream looks like and contents of the pack

Canespor Cream is a white cream filled in an aluminium tube with inner lacquer and polyethylene screw cap. A membrane is also included to guarantee the first opening of the tube.

Canespor Cream is available in the following pack sizes: 20 g, 30 g

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation
Holder Bayer Limited
The Atrium,
Blackthorn Road,
Dublin 18,
Ireland

Manufacturer
Kern Pharma
S.L.
Poligono Industrial Colon II, C /
Venus 72, 08228 Terrassa
(Barcelona)
Spain

GP Grenzach Produktions GmbH
Emil-Barell-Str. 7
D-79639 Grenzach-Wyhlen
Germany

This medicinal product is authorised in the Member States of the EEA under the following names:

Ireland Canespor 10mg/g Cream
Finland Canespor 10 mg/g Cream

This leaflet was last revised in October 2018

