Canespro®

Once Daily Bifonazole
Anti-Fungal cream 1%w/w

For external use only

PRODUCT INSERT FOR MALAYSIA MARKET

Active ingredients
Canespro® Once Daily Bifonazole Anti-Fungal Cream 1%w/w contains:
Bifonazole 1%

Product Description
White & soft cream.

Pharmacodynamic
Pharmacotherapeutic group: Anti-fungals for dermatological use
-Bifonazole ATC Code: DD1AC10

Mode of action
Bifonazole is an imidazole derivative with a broad antimycotic spectrum, which includes dermatophytes, yeasts, moulds and other fungi such as *Malassezia furfur*. It is also effective against *Corynebacterium minutissimum*. Bifonazole exerts its anti-fungal action by inhibiting the biosynthesis of ergosterol on two different levels, thereby distinguishing bifonazole both from other azole derivatives and from other anti-fungals which act only on a single level. Inhibition of ergosterol synthesis leads to structural and functional impairment of the cytoplasmic membrane. The resistance situation for bifonazole is favorable. Primary resistant variants of sensitive fungal species are very rare. Investigations so far did not provide any evidence of a development of secondary resistance in primarily sensitive strains.

Pharmacokinetic
Absorption
Bifonazole penetrates well into infected skin layers. 6 hours after administration concentrations in the various skin layers reach from 1000 µg/cm^3 in the top layer of the epidermis (stratum corneum) to 5 µg/cm^3 in the stratum papillare. All concentrations determined are thus within a range of reliable antimycotic activity.

Indications
- Treatment of skin mycoses caused by dermatophytes, yeasts, moulds, and other fungi (e.g. athlete's foot, fungal infection of the hand, ringworms, jock itch, white spots, superficial fungal skin infections & other tinea conditions).
- Treatment of erythrasma (skin redness).

Dosage & application
Posology
To achieve a lasting cure, treatment with bifonazole must be carried out reliably and over an adequate period. The usual periods of treatment are summarized in the table below:

Indication	Duration of treatment
Foot mycoses (athlete's foot)	3 weeks
Mycoses of the trunk, hands and skin folds (ring-worms. fungal infection of the hands, jock itch)	2-3 weeks
White spots	2 weeks
Erythrasma (skin redness)	2 weeks
Superficial candidiasis of the skin	2-4 weeks

Method of administration
Once a day, preferably in the evening, before going to bed. It should be applied thinly to the affected skin area and rubbed in. A small amount of cream is generally sufficient to treat an area of about the size of the palm of hand.

Use in Children
No in-depth studies have been performed in the pediatric population (0 to 18 years). From a survey of the clinical data reported there is no indication that harmful effects should be anticipated in pediatric population. However, in neonates (0 to 27 days), infants and toddlers (28 days to 23 months), the medicinal product should only be used under medical supervision.

Contraindication
Hypersensitivity to the active substance or to any of the excipients.

Special Warning and Precautions for Use
Patients with a history of hypersensitivity reactions to other imidazole antifungal agents (e.g. econazole, clotrimazole, miconazole) must take bifonazole containing products with caution. If symptoms continue/persist after treatment, seek medical advice.
Patients on warfarin therapy should be monitored when bifonazole is used concomitantly. Some of the excipients may reduce the effectiveness of latex products such as condoms and diaphragms when applied to genital area. The effect is temporary and occurs only during treatment.
Keep medicine out of the reach of children. Avoid contact with eyes. Do not swallow.

Pregnancy
Preclinical safety data and pharmacokinetic data in humans give no indication that harmful effects on the mother and child should be anticipated when bifonazole is used during pregnancy. However, no clinical data are available. As a precautionary measure, it is preferable to avoid the use of bifonazole during the first trimester of pregnancy.

Lactation
It is unknown whether bifonazole is excreted in human breast milk. The excretion of bifonazole in milk has been studied in animals. Available pharmacodynamic/toxicological data in animals have shown excretion of bifonazole/metabolites in milk. Breastfeeding should be discontinued during treatment with bifonazole.

Drug interaction
Limited data suggest that an interaction between topical bifonazole and warfarin may be possible, leading to increases in the international normalized ratio (INR). If bifonazole is used in a patient on warfarin therapy, they should be appropriately monitored.

Adverse effects
The following adverse reactions have been identified during post-approval use of bifonazole. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency.
- General disorders and administration site conditions
- Administration site pain, peripheral edema (at administration site)
- Skin and subcutaneous tissue disorders

Contact dermatitis, allergic dermatitis, erythema, pruritus, rash, urticaria, blister, skin exfoliation, eczema, dry skin, skin irritation, skin maceration, skin burning sensation.
These side effects are reversible after discontinuation of the treatment.

Overdosage
No risk of acute intoxication is seen as it is unlikely to occur following a single dermal application of an overdose (application over a large area under conditions favorable to absorption) or inadvertent oral ingestion.
However, in the event of accidental oral ingestion, routine measures such as gastric lavage should be performed only if clinical symptoms of overdosage become apparent (e.g. dizziness, nausea or vomiting). Gastric lavage should be carried out only if the airway can be protected adequately.

Storage: Store below 30°C.
Shelf life: Please refers to labels.
Presentation: Tube of 15g cream.
Manufacturer: GP Grenzach Produktions GmbH,
Emil-Barell-Strasse 7, 79639 Grenzach-Wyhlen, Germany For Bayer Consumer Care AG, Basel, Switzerland
Product Registration Holder: Bayer Co. (Malaysia) Sdn Bhd - 25-03 & 25-04, Level 25, IMAZIUM, No. 8, Jalan SS21/37, Damansara Uptown, 47400 Petaling Jaya, Selangor

PATIENT INFORMATION LEAFLET FOR SINGAPORE MARKET

Product Description
Canespro cream is a white cream packaged in an aluminum tube with inner lacquer (epoxy phenolic resin) and polyethylene (PE) screw cap. Canespro cream is available in tubes of 15g.

What are the ingredients in Canespro cream?
100g Canespro cream contains 1 g bifonazole as active ingredient. Canespro cream also contains benzyl alcohol, cetostearyl alcohol, cetyl palmitate, Octyldodecanol, Polysorbate 60, purified water and sorbitan stearate as excipients.

What is Canespro cream used for?
Canespro cream is a topical broad spectrum antifungal cream used to treat athlete's foot and other fungal skin infections such as tinea, ringworm and yeast infections of the skin.
If you are not sure whether you should start using Canespro cream, talk to your doctor or pharmacist.

How should Canespro cream be used?
Clean and dry the affected area thoroughly. Apply Canespro cream thinly and evenly to the affected skin area once daily, preferably at night before going to bed, and rub it in gently. To achieve a lasting cure, treatment with bifonazole must be carried out reliably and over an adequate period. The usual periods of treatment are summarized in the table below:

Indication	Duration of treatment
Foot mycoses (Tinea pedis, tinea pedum interdigitalis)	3 weeks
Mycoses of the trunk, hands and skin folds (Tinea corporis, tinea manuum, tinea inguinalis)	2-3 weeks
Pityriasis versicolor	2 weeks
Superficial candidiasis of the skin	2-4 weeks

Continue treatment for 2 weeks after symptoms have subsided to avoid recurrence of the infection. For treatment of 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 athlete's foot, such as itching and 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. If you forget to use Canespro cream, apply the cream as soon as possible and then continue the rest of your treatment as usual.

When should you not use Canespro cream?
Do not use Canespro cream if you are allergic or hypersensitive bifonazole or any of the ingredients in this product (cetostearyl alcohol may cause local skin reactions, e.g. rash, itching or redness)

What precautions should you note while using Canespro cream?
- Do not use in neonates (0 to 27 days), infants and toddlers (28 days to 23 months) unless under medical supervision.
- Do not use Canespro cream if you are pregnant or breast-feeding, unless on the advice of your doctor.
- Patients with a history of hypersensitivity reactions to other imidazole antifungal agents (e.g. econazole, clotrimazole, miconazole) must use bifonazole containing products with caution.
- As with all other medications, keep Canespro Once Daily cream out of the reach of children.
- Canespro cream should not come into contact with your eyes.
- Canespro cream is meant for external use only; do not swallow. If you accidentally get cream in your eyes or mouth, wash immediately with water and contact your doctor.
- Patients on warfarin therapy should be monitored when bifonazole is used concomitantly.
- Some of the excipients may reduce the effectiveness of latex products such as condoms and diaphragms when applied to genital area. The effect is temporary and occurs only during treatment.

What are the undesirable effects associated with the use of Canespro cream?
Skin reactions (slight irritation, reddening, peeling or burning) may occur. These side effects are reversible after discontinuation of the treatment. Should any undesirable effects occur, please consult your healthcare professional.

What other medicines should be avoided whilst taking this medicine?
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).

What should you do in case of an overdose?
No risk of acute intoxication is seen as it is unlikely to occur following a single dermal application of an overdose (application over a large area under conditions favorable to absorption) or inadvertent oral ingestion. However, in the event of an overdose or accidental ingestion, seek medical help immediately. Take this leaflet with you to show what you are taking or have taken.

When should you consult your doctor?
Consult your doctor if you:
- Experience no improvement of symptoms even after using Canespro cream for about 7 days, worsening of symptoms or hypersensitivity
- Have allergies to any other medicine or any other substances such as foods, preservatives or colours
- Are pregnant, suspect that you are pregnant or are breastfeeding. Your doctor will discuss with you the risks and benefits of using this product while pregnant or breastfeeding.
- Are using any other creams, ointments or lotions, or taking any medicine. This includes any that you buy without a prescription from a pharmacy, supermarket or health food shop.

How should you store Canespro cream?
Store Canespro cream in a cool dry place, below 30˚C. Keep all medication out of reach of children. After first opening of the container, Canespro cream can be used for up to 16 months. However, do not use Canespro cream after the expiry date.
For the shelf-life, please refer to labels.
Imported and marketed by: Bayer (South East Asia) Pte Ltd – 2 Tanjong Katong Road, #07-01, Paya Lebar Quarter 3, Singapore 437161
SIN15415P

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