PROFESSIONAL INFORMATION

SCHEDULING STATUS: S1

PROPRIETARY NAME AND DOSAGE FORM:

CANESPOR CREAM
CANESPOR SOLUTION

COMPOSITION:

CREAM: Bifonazole 10 mg

(see excipients listed below)

Benzyl alcohol (as preservative) 2 %

Cetostearyl alcohol,

Cetyl palmitate,

2-octyldodecanol,

Polysorbate 60,

Purified water,

Sorbitan monostearate.

SOLUTION: Bifonazole 10 mg

(see excipients listed below)

Ethanol

Isopropyl myristate.

CATEGORY AND CLASS:

A.13.9.2. Fungicides

PHARMACOLOGICAL ACTION:

Bifonazole is a broad-spectrum antifungal, which suppresses cell wall synthesis.

Its *in vitro* activity against dermatophytes (e.g. *Trichophyton* spp.) is primarily fungicidal whereas that against yeasts is primarily fungistatic.

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PHARMACODYNAMIC PROPERTIES:

Bifonazole is an imidazole derivative with a broad antimycotic spectrum which includes dermatophytes, yeasts, moulds, and other fungi such as *Malassezia furfur*. It also has activity against *Corynebacterium minutissimum*.

Bifonazole inhibits the biosynthesis of ergosterol on two different levels. Inhibition of ergosterol synthesis leads to structural and functional impairment of the cytoplasmic membrane.

PHARMACOKINETIC PROPERTIES:

Absorption

Bifonazole penetrates well into infected skin layers. 6 hours after administration, concentrations in the various skin layers reach from 1000 $\mu g/cm^3$ in the top layer of the epidermis (stratum corneum) to 5 $\mu g/cm^3$ in the stratum papillare.

Pharmacokinetic investigations after topical application to intact human skin have shown that only a small amount of bifonazole is absorbed (0.6 - 0.8 % of the dose); the resulting serum concentrations were always below the detection limit (i.e. < 1 ng/ml). Slight absorption was observed only after application to inflamed skin (2 - 4 % of the respective dose).

INDICATIONS:

Indicated in mycoses of the skin and mucocutaneous parts due to dermatophytes, *Candida* species, *Malassezia furfur*, *Corynebacterium minutissimum* and *Aspergillus* species.

CONTRA-INDICATIONS:

Hypersensitivity to bifonazole, cetyl stearyl alcohol (cream) or to any other of the excipients of the product.

WARNINGS AND SPECIAL PRECAUTIONS:

Solution is inflammable. Keep away from open flame.

For external use only.

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Special Precautions

Keep CANESPOR out of the reach of children

Avoid contact with eyes.

CANESPOR: In cases of known hypersensitivity to cetostearyl alcohol, it is advisable to use a cetostearyl alcohol-free formulation (e.g. bifonazole solution) instead of the cream.

INTERACTIONS:

Not known.

HUMAN REPRODUCTION:

Safety in pregnancy and lactation has not been established.

In the first 3 months of pregnancy, CANESPOR should not be used without first consulting a doctor.

DOSAGE AND DIRECTIONS FOR USE:

CANESPOR Cream or Solution is used once daily, preferably before retiring. It is applied thinly to the affected skin areas, and rubbed in. Usually only a few drops (about 3 drops) of solution or when using the pump spray, 1 or 2 depressions of the spray head, or a small amount (approximately ½ cm) of cream, will suffice for the treatment of an area the size of the palm of the hand.

For hygienic support of treatment, it is advisable to wash and thoroughly dry the skin areas affected before applying CANESPOR Cream or Solution.

Treatment with CANESPOR Cream or Solution should not be stopped when the acute inflammatory symptoms and signs have subsided, but depending on the disease being treated, be continued for 2 to 4 weeks. Safety for periods exceeding 4 weeks has not been established.

CANESPOR preparations are odourless and can be washed off.

CANESPOR Cream and Solution should not be applied to the eyes.

Candida balanitis should be treated with CANESPOR Cream only.

Safety and efficacy in children have not been established.

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SIDE EFFECTS:

The most common Adverse Reactions based on clinical studies and PMS studies with all topical bifonazole formulations and sorted by frequency (n = 36351 patients, status 30.11.1998)

Incidence of frequency ≥ 0.01 % < 0.1 %

Body as a whole: allergic reaction

Incidence of frequency ≥ 0.1 % < 1 %

Body as a whole: pain

Skin and appendages: contact dermatitis, eczema, pruritus, rash (vesiculobullous), dry skin, skin disorder, transient reddening, burning sensation.

These side effects are reversible after discontinuation of the treatment.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS:

Topical absorption of bifonazole is minimal and therefore no systemic effect need be expected.

IDENTIFICATION:

CANESPOR CREAM: Soft white cream.

CANESPOR SOLUTION: Clear, colourless liquid.

PRESENTATION:

CANESPOR CREAM: Tubes of 15 g

CANESPOR SOLUTION: Bottles of 15 ml

Spray bottles of 25 ml

STORAGE INSTRUCTIONS:

Store at or below 25 °C.

Keep out of reach of children.

CANESPOR solution is inflammable. Keep away from open flame

For external use only.

PROFESSIONAL INFORMATION

REGISTRATION NUMBER:

CANESPOR CREAM: R/13.9.2/203

CANESPOR SOLUTION: R/13.9.2/204

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Bayer (Pty) Ltd

27 Wrench Road

Isando

1600

Co. Reg. No 1968/011192/07

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION:

Date on the registration certificate of the medicine: 07/09/1984

Date of publication of this professional information: 02/03/2012

Cream: Manufactured and packed by Kern Pharma S.L., Spain under licence by Bayer AG.

Solution: Manufactured and packed by KVP Pharma and Veterinar Produkte, Germany under licence by Bayer AG.