SCHEDULING STATUS: S1

PROPRIETARY NAME AND DOSAGE FORM:

CANESTEN®
Topical Cream

COMPOSITION:

Each gram contains: Clotrimazole 10 mg/ g

Inactive ingredients: Benzyl alcohol 2 % (as preservative), cetostearyl alcohol, cetyl ester wax, octyldodecanol, polysorbate 60, sorbitan monostearate and purified water.

CATEGORY AND CLASS:

A 20.2.2 Fungicides

PHARMACOLOGICAL ACTION:

A broad spectrum antimycotic acting as fungicide.

INDICATIONS:

The range of indications is:

1. All dermatomycoses due to dermatophytes (e.g. *Trichophyton* species).

2. All dermatomycoses due to yeasts (e.g. *Candida* species).

3. Dermatomycoses due to moulds and other fungi.

4. Skin diseases with secondary infection by these fungi.

The dermatomycoses mentioned under 1 - 4 include among others:

1. Mycoses of the skin and skin folds, (e.g. fungal infections of the groin, perineum, axillae, Dhobies' or jock itch and barber's itch.)

2. Ringworm.

3. Interdigital mycoses e.g. athlete's foot.

4. *Candida vulvitis* (vulval thrush).

5. *Candida balanitis,* (thrush of the glans penis).

6. Pityriasis (Tinea) versicolor.

7. Erythrasma.

8. Paronychias, associated with nail mycoses, (fungal infections of the tissues adjacent to the nail of a finger or toe).

CONTRA-INDICATIONS:

Possible hypersensitivity to clotrimazole and / or cetostearyl alcohol (cream).

WARNINGS AND SPECIAL PRECAUTIONS:

For external use only.

Direct contact with Canesten® Topical Cream may reduce the effectiveness and safety of latex products such as condoms and diaphragms. The effect is temporary and occurs only during treatment.

DOSAGE AND DIRECTIONS FOR USE:

Apply thinly to the affected areas 2 - 3 times daily and rub in. A small amount of cream is sufficient for an area about the size of the palm. Successful treatment demands that CANESTEN® Topical Cream be applied correctly and over a sufficiently long period of time.

The duration of treatment varies. In general, it is 3 - 4 weeks in the case of dermatomycoses due to dermatophytes and yeasts; in *Candida vulvitis* and *Candida balanitis*, 1 - 2 weeks; and approximately 2 - 4 weeks in Erythrasma and 1 - 3 weeks in Pityriasis versicolor.

TREATMENT OF FUNGAL INFECTION SHOULD BE CONTINUED FOR APPROXIMATELY 2 WEEKS AFTER THE DISAPPEARANCE OF ALL SYMPTOMS DESPITE A RAPID, SUBJECTIVE IMPROVEMENT, IN ORDER TO PREVENT RELAPSE.

Athlete's foot: Always dry the feet carefully, especially between the toes.

CANESTEN® Topical Cream is odourless, can be washed off and do not stain. Cosmetically well accepted.

SIDE EFFECTS:

Not intended for ophthalmic use. Local reactions including skin irritation and burning may occur. Contact allergic dermatitis has been reported. In cases of systemic absorption, lower abdominal cramps, increase in urinary frequency or skin rash may occur.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

See side-effects. In case of accidental ingestion, gastrointestinal disturbances and central nervous system depression may occur. Treatment is symptomatic and supportive.

IDENTIFICATION:

A soft, white cream.

PRESENTATION:

Tube of 20 g.

STORAGE DIRECTIONS:

Store at or below 25 ºC.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

E/20.2.2/49

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

Bayer (Pty) Ltd, 27 Wrench Road, Isando, 1600,

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