

SCHEDULING STATUS:

S1

PROPRIETARY NAME AND DOSAGE FORM:

CLOTRIMAZOLE TOPICAL BIOTECH

COMPOSITION:

Each 1 g of cream contains: Clotrimazole 10,0 mg

Preservative:

Nipastat 0,275 % m/m

Imidurea 0,300 % m/m

PHARMACOLOGICAL CLASSIFICATION:

A 20.2.2 Fungicides.

PHARMACOLOGICAL ACTION:

A broad spectrum antimycotic with fungicidal properties.

INDICATIONS:

- All dermatomycoses due to dermatophytes (e.g. Trichophyton species).
- Dermatomycoses due to moulds and other fungi.
- Skin disease with secondary infection by these fungi.

The dermatomycoses mentioned above include among others:

- Mycoses of the skin and skin folds.
- Ringworm.
- Interdigital mycoses e.g. athletes foot.
- Pityriasis versicolor.
- Erythrasma.
- Paronychias (associated with nail mycoses).

CONTRA-INDICATIONS:

Possible sensitivity to clotrimazole.

DOSAGE AND DIRECTIONS FOR USE:

Apply thinly to the affected areas 2-3 times daily and rub in.

Successful treatment demands that CLOTRIMAZOLE TOPICAL BIOTECH 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 approximately 3 weeks in Erythrasma and 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.

Athletes foot: Always dry the feet carefully, especially between the toes.

CLOTRIMAZOLE TOPICAL BIOTECH cream is odourless, can be washed off and does not stain.

CLOTRIMAZOLE TOPICAL BIOTECH cream is not indicated for ophthalmic use and should be used with caution around the eyes.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Local reactions including irritation and burning may occur. Contact allergic dermatitis can occur. If this occurs, treatment should be discontinued.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

See SIDE-EFFECTS AND SPECIAL PRECAUTIONS. In case of accidental ingestion, gastro intestinal disturbances and central nervous system depression may occur.

Treatment is symptomatic and supportive.

IDENTIFICATION:

A soft white cream.

PRESENTATION:

Tube of 20 g in an outer carton.

STORAGE INSTRUCTIONS:

Store at or below 25 °C in a well-closed container, protected from light.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

27/20.2.2/0337

NAME AND BUSINESS ADDRESS OF APPLICANT:

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South Africa

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SKEDULERINGSSTATUS:

S1

EIENDOMSNAAM EN DOSEERVORM:

CLOTRIMAZOLE TOPICAL BIOTECH

SAMESTELLING:

Elke 1 g room bevat: Klotrimasool 10,0 mg

Preserveermiddels:

Nipastat 0,275% m/m

Imidurea 0,300% m/m

FARMAKOLOGIESE KLASSIFIKASIE:

A 20.2.2 Swamdoders.

FARMAKOLOGIESE WERKING:

’n Bree-spektrum antimikotiese middel met ’n swamdodende werking.

INDIKASIES:

- Alle dermatomikoses veroorsaak deur dermatofiete (bv. *Trichophyton* spesies).
- Dermatikoses veroorsaak deur skimmels en fungusse.
- Velsiektes met sekondêre infeksie deur hierdie fungusse.

Die dermatomikose hierbo genoem sluit onder andere die volgende in:

- Mikose van die huid en huidvoue.
- Omlope.
- Interdigitale mikose (bv. Voetskimmel).
- Pityriases versicolor.
- Eritrasme.
- Paranogie (naelskimmel).

KONTRA-INDIKASIES:

Moontlike gevoeligheid vir klotrimasool.

DOSIS EN GEBRUIKSAANWYSINGS:

Wend 2-3 keer per dag baie dun aan op die aangetaste dele en vryf in. ’n Suksesvolle behandeling vereis gereelde toediening oor ’n lang tydperk. Die tydperk van behandeling verskil. Normaalweg duur dit 3-4 weke in die geval van dermatomikose veroorsaak deur dermatofiete en ongeveer 3 weke in die geval van Eritrasme en Pityriases versicolor.

Behandeling teen fungusbesmetting moet minstens vir 2 weke voortgesit word na verdwyning van die simptome, ondanks vinnige verbetering ten einde hervatting te voorkom.

Voetskimmel: Droog voete altyd goed af, veral tussen die tone. CLOTRIMAZOLE TOPICAL BIOTECH room is reukloos, kan afgewas word en vlek nie. CLOTRIMAZOLE TOPICAL BIOTECH word nie aangedui vir ooggebruik nie, en moet dus versigtig rondom die oë gebruik word.

NEWE EFFEKTE EN SPESIALE VOORSORGMAATREËLS:

Lokale reaksies wat irritasies en branderigheid insluit mg voorkom.

Kontak allergiese dermatitis kan voorkom. As dit gebeur, moet behandeling gestaak word.

BEKENDE SIMPTOME VAN OORDOSERING EN DIE BEHANDELING DAARVAN:

Sien NEWE EFFEKTE EN SPESIALE VOORSORGMAATREËLS.

In die geval van toevallige inname kan dit maagderm-steurnisse en sentrale senuwees-stelsel onderdrukking veroorsaak. Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE:

’n Sagte wit room.

AANBIEDING:

Buis met 20g room in ’n karton.

BERGINGSVOORSKRIFTE:

Bewaar teen of benede 25°C in ’n dig geseëde houer, beskerm teen lig.

HOU BUITE BEREIK VAN KINDERS.

REGISTRASIE NOMMER:

27/20.2.2/0337

NAAM EN BESIGHEIDSADRES VAN DIE EIENAAR VAN DIE SERTIFIKAAT VAN REGISTRASIE:

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Suid Afrika

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