SCHEDULING STATUS: S1

PROPRIETARY NAME AND DOSAGE FORM:

COVAREX CREAM

COMPOSITION:
COVAREX contains:

Miconazole Nitrate	2 g per 100 g
Preservatives:	
Imidurea	0,2 % m/m
Methyl paraben	0,15 % m/m
Sodium propyl paraben	0,15 % m/m
Anti-oxidant:	
Butyl Hydroxytoluene	0,02 % m/m

PHARMACOLOGICAL CLASSIFICATION:
A 13.9.2 Fungicides
PHARMACOLOGICAL ACTION:
Miconazole nitrate is a fungistatic. In *Candida albicans* it inhibits transformation of blastospores into invasive mycelial form.
INDICATIONS:
COVAREX is indicated in the topical treatment of cutaneous candidiasis caused by *Candida albicans* and of *tinea corporis* (ringworm of the body), *tinea cruris* (ringworm of the groin) and *tinea pedis* (ringworm of the foot/athletes foot) caused by *Trichophyton rubrum, T. mentagrophytes,* and *Epidermophyton floccosum.*
CONTRAINDICATIONS:
Hypersensitivity to miconazole nitrate or any other ingredients of **COVAREX.**
WARNING AND SPECIAL PRECAUTIONS:
For external use only.
Continue to apply **COVAREX** for the full period of treatment as indicated. (see: **DOSAGE AND DIRECTIONS FOR USE**)
Special Precautions:
Safety of topical use during pregnancy and lactation has not been established.
DOSAGE AND DIRECTIONS FOR USE:
Apply **COVAREX** twice daily (morning and evening) for cutaneous candidiasis and *tinea corporis, tinea cruris* and *tinea pedis.*
To reduce the possibility of recurrence, apply **COVAREX** for 2 weeks in the treatment of Candida infections, *tinea cruris* and *tinea corporis* and apply **COVAREX** for one month in the treatment of *tinea pedis*.
Avoid occlusive dressings when this medication is used in the treatment conditions caused by *Candida albicans* as it provides conditions that favour growth of yeast and release of its irritating endotoxin
SIDE EFFECTS:
COVAREX may cause blistering, burning, redness, skin rash or other sign of skin irritation and contact dermatitis not present before therapy.
After prolonged and extensive application, systemic absorption cannot be excluded that may result in side effects usually associated with systemically administered miconazole nitrate such as anaemia, hepatotoxicity, thrombocytopenia, dizziness, drowsiness, headache, flushing or redness of face or skin and gastrointestinal disturbances.
KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF IT TREATMENT:
No known symptoms. (See **SIDE EFFECTS)** Treatment is symptomatic and supportive.
IDENTIFICATION:
A smooth white to greyish-white cream.
PRESENTATION:
Polyethylene laminated aluminium tubes of 25 g, 30 g, 40 g and 50 g with a white screw cap.
STORAGE INSTRUCTIONS:
Store at or below 25 °C and do not freeze.
For external use only.
KEEP OUT OF THE REACH OF CHILDREN.
REGISTRATION NUMBER:
A 33/13.9.2/0124

Namibian Reg. No.: 12/13.9.2/0123
Namibian Scheduling Status: NS1

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
Glenmark Pharmaceuticals South Africa (Pty) LTD
34 Monte Carlo Crescent
Kyalami Business Park
Midrand, 1685
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