1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S1

PROPRIETARY NAME AND DOSAGE FORM

CANDIZOLE TOPICAL CREAM

COMPOSITION

Each 20 g of CANDIZOLE TOPICAL CREAM contains 200 mg of clotrimazole.

Excipients:

Arlacel, benzyl alcohol, cetostearyl alcohol, liquid paraffin, polysorbate, propylene glycol, purified water, white soft paraffin

Preservative:

Benzyl alcohol 1 % *m/m*

CATEGORY AND CLASS

A 20.2.2 Fungicides

PHARMACOLOGICAL ACTION

A broad-spectrum anti-myotic acting as a fungicide.

INDICATIONS

The range of indications is:

1. Dermatomycoses due to dermatophytes (e.g. *Trychophyton* species).

2. 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.

Dermatomycoses mentioned above include among others:

1. Ringworm.
2. Athlete's foot.
3. Pityriasis versicolor.
4. Mycoses of the skin and skin folds.
5. Candida vulvitis and balanitis.
6. Paronychia (inflammation including the folds of tissue surrounding the finger nail).

CONTRAINDICATIONS

Patients with a known hypersensitivity to clotrimazole.

WARNINGS AND SPECIAL PRECAUTIONS

FOR EXTERNAL USE ONLY.

If general irritation becomes uncomfortable, the preparation should be discontinued and appropriate corrective therapy instituted.

CANDIZOLE TOPICAL CREAM is not indicated for ophthalmic use and it should be used with caution around eyes.

INTERACTIONS

Not known.

HUMAN REPRODUCTION

Not known.

DOSAGE AND DIRECTIONS FOR USE

Apply lightly to the affected and surrounding area twice daily (morning and evening).

Treatment should continue for at least 2 weeks after all symptoms have disappeared in order to prevent relapse.

SIDE EFFECTS

Local reactions including irritation and burning may occur in patients treated topically; contact allergic dermatitis has been reported.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

Symptoms

Gastrointestinal disturbance, urinary symptoms, elevation of liver enzymes, neutropenia and mental depression have been reported after administration of clotrimazole by mouth.

Treatment

Treatment is supportive and symptomatic.

IDENTIFICATION

A soft, smooth white cream.

PRESENTATION

20 g is packed in an aluminium tube sealed with a white high density polyethylene cone shaped cap. The tube is then placed in a unit cardboard carton together with a leaflet.

STORAGE INSTRUCTIONS

Store at or below 25 °C.

Protect from light.

Keep in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

P/20.2.2/164

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

PHARMACARE LIMITED

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DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

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