PACKAGE INSERT

SCHEDULING STATUS: S1

PROPRIETARY NAME (AND DOSAGE FORM):

CLOMADERM (CREAM)

COMPOSITION:

Each 1 g of cream contains:

Clotrimazole	10 mg	
Preservatives:		
Nipastat	0,275	% m/m
Biopure 100	0,3	% m/m

PHARMACOLOGICAL CLASSIFICATION:

A .20.2.2 Fungicides.

PHARMACOLOGICAL ACTION:

A broad spectrum antimycotic with fungicidal properties.

INDICATIONS:

Clomaderm cream indications are:

1. All dermatomycoses due to dermatophytes (e.g. Trichophyton species)
2. Dermatomycoses due to moulds and other fungi.
3. Skin diseases with secondary infection by these fungi.

The dermotomycoses mentioned under 1-3 include among others:

1. Mycoses of the skin and skin fold.
2. Ringworm.
3. Interdigital mycoses, e.g. athlete's foot.
4. Pityriasis versicolor.
5. Erythrasma.
6. Paronychias (associated with nail mycoses).

CONTRA-INDICATIONS:

Possible hypersensitivity to clotrimazole.

DOSAGE AND DIRECTIONS FOR USE:

For external use only.

Apply thinly to the affected areas 2 - 3 times daily and rub in. Successful treatment demands that **Clomaderm** 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.

Athlete's foot: Always dry the feet carefully, especially between the toes. **Clomaderm** is odourless, can be washed off and does not stain.

Clomaderm is not indicated for opthalmic 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 packed into a unit carton.

STORAGE INSTRUCTIONS:

Store below 25 °C, in a dry place.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

28/20.2.2/0419

NAME AND BUSINESS ADDRESS OF APPLICANT:

Gulf Drug Company (PTY) LTD.
22 Burnside Drive
Old Mill Industrial Park
Mount Edgecombe
4300

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2 November 1993