1.5.5 Clean Professional Information

SCHEDULING STATUS

S1

1. NAME OF THE MEDICINE

CANDASPOR® CREAM

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 g of cream contains:

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

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Cream

A soft white cream

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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 1-3 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).

4.2 Posology and method of administration

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 **CANDASPOR® 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.

CANDASPOR® CREAM is odourless, can be washed off and do not stain.

4.3 Contraindications

- Hypersensitivity to clotrimazole or to any of the excipients listed in section 6.1.

4.4Special warnings and precautions for use

For external use only.

- Direct contact with **CANDASPOR® CREAM** may reduce the effectiveness and safety of latex products such as condoms and diaphragms. The effect is temporary and occurs only during treatment.
- Cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis)
- **CANDASPOR® CREAM** is not indicated for opthalmic use and should be used with caution around the eyes.

4.5 Interaction with other medicines and other forms of interaction

Laboratory tests have suggested that, when used together, this product may cause damage to latex contraceptives. Consequently the effectiveness of such contraceptives may be reduced. Patients should be advised to use alternative precautions for at least five days after using this product.

4.6 Fertility, pregnancy and lactation

Fertility

No human studies of the effects of clotrimazole on fertility have been performed, however, animal studies have not demonstrated any effects of the drug on fertility.

Pregnancy:

There is a limited amount of data from the use of clotrimazole in pregnant women. Animal studies with clotrimazole have shown reproductive toxicity at high oral doses (see section 5.3).

At the low systemic exposures of clotrimazole following topical treatment, harmful effects with respect to reproductive toxicity are not predicted. Clotrimazole can be used during pregnancy, but only under the supervision of a physician or midwife.

Lactation:

Available pharmacodynamic/toxicological data in animals have shown excretion of clotrimazole/metabolites in milk after intravenous administration (see section 5.3). A risk to the suckling child cannot be excluded. A decision must be made
whether to discontinue breast-feeding or to discontinue/abstain from clotrimazole therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

4.7 Effects on ability to drive and use machines

CANDASPOR®CREAM has no or negligible influence on the ability to drive or use machinery.

4.8 Undesirable effects

System Class	Frequent	Less Frequent	Frequency Unknown
Immune system disorders			Allergic reaction (syncope, hypotension, dyspnea, urticaria).
Skin and subcutaneous			Blisters, discomfort/pain, oedema, erythema, irritation, peeling/exfoliation, pruritus, rash, stinging/burning,

tissue disorders:			allergic dermatitis

Treatment should be discontinued.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form"**, found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/Index/8

4.9 Overdose

In case of accidental ingestion, gastro-intestinal disturbances and central nervous system depression may occur. Treatment is symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A 20.2.2. Fungicides

Pharmacotherapeutic group: Antifungals for topical use – imidazole and triazole derivatives.

ATC Code: D01A C01

Mechanism of action

CANDASPOR® CREAM is a broad spectrum antimycotic with fungicidal properties.

Clotrimazole acts against fungi by inhibiting ergosterol synthesis. Inhibition of ergosterol synthesis leads to structural and functional impairment of the fungal cytoplasmic membrane.

Clotrimazole has a broad antimycotic spectrum of action in vitro and in vivo, which includes dermatophytes, yeasts and moulds, etc.

Under appropriate test conditions, the MIC values for these types of fungi are in the region of less than 0,062 -8,0 µg/ml substrate. The mode of action of clotrimazole is primarily fungistatic or fungicidal depending on the concentration of clotrimazole at the site of infection. *In vitro* activity is limited to proliferating fungal elements; fungal spores are only slightly sensitive.

In addition to its antimycotic action, clotrimazole also acts on gram-positive microorganisms (Streptococci /Staphylococci / Gardnerella vaginalis), and gram-negative microorganisms (Bacteroides).

In vitro clotrimazole inhibits the multiplication of Corynebacteria and gram-positive cocci - with the exception of Enterococci - in concentrations of 0,5-10 µg/ml substrate.

Primarily resistant variants of sensitive fungal species are very rare; the development of secondary resistance by sensitive fungi has so far only been observed in very isolated cases under therapeutic conditions.

5.2 Pharmacokinetic properties

Pharmacokinetic investigations after dermal application have shown that clotrimazole is minimally absorbed from the intact or inflamed skin into the human blood circulation. The resulting peak serum concentrations of clotrimazole were below the detection limit of 0,001 µg/ml, suggesting that clotrimazole applied topically is unlikely to lead to measurable systemic effects or side effects.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Biopure 100, ceteareth-25, ceteareth-6 & stearyl alcohol, cetostearyl alcohol, liquid paraffin, nipastat, propylene glycol.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 Months

6.4 Special precautions for storage

Store at or below 25 °C.

6.5 Nature and contents of container

Tube of 20 g.

6.6 Special precautions for disposal and other handling

No special requirements for disposal.

7 HOLDER OF CERTIFICATE OF REGISTRATION

RANBAXY PHARMACEUTICALS (PTY) LTD

14 LAUTRE ROAD

STORMILL, EXT.1

ROODEPOORT

1724, SOUTH AFRICA

8 REGISTRATION NUMBER(S)

Y/20.2.2/289 (S.A)

S3 BOT 0500760 (Botswana)
NS1 04/20.2.2/0999 (Namibia)

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

The date on the registration certificate of the medicine:

08 August 1991

10 DATE OF REVISON OF THE TEXT

Will be allocated by SAHPRA upon approval of update