SCHEDULING STATUS

S1

1. NAME OF THE MEDICINE

FUNGISTOP TOPICAL 1 % *m/m* cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 g of cream contains 10 mg clotrimazole.

Excipients with known effect:

Preservatives:

Nipastat 0,275 % *m/m*

Imidurea 0,300 % *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 disease with secondary infection by these fungi.

The dermatomycoses mentioned under 1 – 4 include among others:

- Mycoses of the skin and skin folds (e.g. fungal infections of the groin, perineum, axillae, Dhobies' or jock itch and barber's itch.)
- Ringworm.
- Interdigital mycoses e.g. athlete's foot.
- Candida vulvitis (vulval thrush).
- Candida balanitis (thrush of the glans penis).
- Pityriasis (Tinea) versicolor.
- Erythrasma.
- Paronychia (associated with nail mycoses).

4.2 Posology and method of administration

Posology

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 FUNGISTOP TOPICAL 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.

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

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

Method of administration

For topical use.

4.3 Contraindications

Hypersensitivity to clotrimazole or any of the excipients of FUNGISTOP TOPICAL (see section 6.1).

4.4 Special warnings and precautions for use

For external use only. Not for ophthalmic use.

Do not smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with FUNGISTOP TOPICAL burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

Excipients

FUNGISTOP TOPICAL contains cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis).

4.5 Interaction with other medicines and other forms of interaction

FUNGISTOP TOPICAL 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 FUNGISTOP TOPICAL.

4.6 Fertility, pregnancy and lactation

Pregnancy

Safety and efficacy of FUNGISTOP TOPICAL in pregnancy has not been established.

Breastfeeding

Safety and efficacy of FUNGISTOP TOPICAL in breastfeeding has not been established.

Fertility

No human studies of the effects of FUNGISTOP TOPICAL on fertility have been performed; however, animal studies have not demonstrated any effects of FUNGISTOP TOPICAL on fertility.

4.7 Effects on ability to drive and use machines

FUNGISTOP TOPICAL cream has no or negligible influence on the ability to drive or use machines.

4.8 Undesirable effects

As the listed undesirable effects are based on spontaneous reports, assigning an accurate frequency of occurrence for each is not possible.

Tabulated list of adverse reactions

MedDRA System Organ Class	**Frequency**	**Description**
Immune system disorders	*Frequency unknown*	Allergic reaction, anaphylactic reaction, angioedema, hypersensitivity.
Vascular disorders	*Frequency unknown*	Syncope, hypotension.
Respiratory, thoracic and mediastinal disorders	*Frequency unknown*	Dyspnoea.
Skin and	*Frequency unknown*	Blisters, contact allergic dermatitis[1], erythema, paraesthesia,

subcutaneous tissue disorders		skin peeling/ exfoliation, pruritis, rash, urticaria stinging skin/ burning sensation skin.
General disorders and administration site conditions	*Frequency unknown*	Application site irritation, oedema, discomfort/ pain.

[1] If this occurs, 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. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

4.9 Overdose

See section 4.8. In case of accidental ingestion, gastrointestinal 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: D01AC01

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.

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

Propylene glycol

Purified water

Imidurea

Nipastat

Liquid paraffin

Cremophor A25

Cremophor A6

Cetostearyl alcohol.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

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

6.5 Nature and contents of container

20 g printed aluminium tube in an outer carton.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Biotech Laboratories (Pty) Ltd

Ground Floor, Block K West, Central Park

400 16th Road, Randjespark, Midrand 1685

South Africa

8. REGISTRATION NUMBER

27/20.2.2/0337

9. DATE OF FIRST AUTHORISATION/ RENEWAL OF THE AUTHORISATION

August 1992

10. DATE OF REVISION OF THE TEXT

29 September 2023