Summary of product characteristic (SmPC)

1. NAME OF THE MEDICINAL PRODUCT

PRODUCT NAME

GENERIC: CLOTRIMAZOLE CREAM BP 1% w/w

BRAND NAME: CANIMAKS

DESCRIPTION:

White soft cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Clotrimazole BP ..... 1% w/w

Cream Base ..... q.s.

For complete list of excipients refer section 6.1.

3. PHARMACEUTICAL FORM:

Topical, Semi-solid Dosage Form – Cream

4. CLINICAL PARTICULARS

4.1 Therapeutic Indication:

For the treatment of:

- All dermatomycoses due to moulds and other fungi (e.g. Trichophyton species).
- All dermatomycoses due to yeasts (Candida species).
- Skin diseases showing secondary infection with these fungi.
- Candidal nappy rash, vulvitis and balanitis.

4.2 Posology and method of administration:

There is no separate dosage schedule for the young or elderly.
The cream should be applied thinly 2-3 times daily and rubbed in gently. A strip of cream (½ cm long) is enough to treat an area of about the size of the hand. Treatment should be continued for at least one month for dermatophyte infections and at least two weeks for candidal infections.

If the feet are infected they should be washed and dried, especially between the toes, before applying the cream.

4.3 Contraindications:

Hypersensitivity to the active substance or to any of the excipients.

Do not use the cream to treat nail or scalp infections.

4.4 Warning and precautions for use

This product contains cetostearyl alcohol, which may cause local skin reactions (e.g. contact dermatitis).

4.5 Drug Interactions

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 Pregnancy & 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. 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. 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:

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

4.8 Adverse Effects

As the listed undesirable effects are based on spontaneous reports, assigning an accurate frequency of occurrence for each is not possible.
Immune system disorders: allergic reaction (syncope, hypotension, dyspnea, urticaria).
Skin and subcutaneous tissue disorders: blisters, discomfort /pain, oedema, erythema, irritation, peeling/exfoliation, pruritus, rash, stinging/burning.

4.9 Overdose

No risk of acute intoxication is seen as it is unlikely to occur following a single dermal application of an overdose (application over a large area under conditions favourable to absorption) or inadvertent oral ingestion. There is no specific antidote.
However, in the event of accidental oral ingestion, gastric lavage is rarely required and should be considered only if a life-threatening amount of Clotrimazole has been ingested within the preceding hour or if clinical symptoms of overdose become apparent (e.g. dizziness, nausea or vomiting). Gastric lavage should be carried out only if the airway can be protected adequately.

5. PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacodynamic properties:

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

Mechanism of Action

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, 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 mcg/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, Cetomacrogol-1000, Cetostearyl Alcohol, Light Liquid Paraffin, White Soft Paraffin, Methyl Hydroxybenzoate, Propyl Hydroxybenzoate, Disodium Hydrogen Phosphate (Dihydrate), Sodium Dihydrogen Phosphate Dihydrate, Purified Water.

6.2 Incompatibilities

Not Applicable

6.3 Shelf Life

3 years

6.4 Special precautions for storage:

Do not store above 30ºC. Protect from light.
Do not freeze. Do not accept if seal is broken.
Puncture nozzle with piercing point of the cap.
Keep the tube tightly closed after use.
Keep the medicine out of reach of children.
For external use only.

6.5 Nature and contents of container

15gm Aluminium collapsible tube

6.6 Special precautions for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements

7. APPLICANT

Manufactured by:

S Kant
HEALTHCARE Ltd.

1802-1805, G.I.D.C., Phase III,

Vapi - 396 195. Gujarat, INDIA.

8. WHO PREQUALIFICATION REFERENCE NUMBER

Not applicable

9. DATE OF PREQUALIFICATION / RENEWAL OF PREQUALIFICATION

Not applicable

10. DATE OF REVISION OF THE TEXT

11th March 2019