National Agency for Food & Drug Administration & Control (NAFDAC)

Registration & Regulatory Affairs (R & R) Directorate

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC) TEMPLATE

1. NAME OF THE MEDICINAL PRODUCT

Candid Dusting Powder (Clotrimazole USP 1%)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Clotrimazole USP 1% w/w

Purified Talc base q.s

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Powder for topical application

4. Clinical particulars

4.1 Therapeutic indications

Candid Dusting Powder is indicated for the topical treatment of the superficial fungal infections due to susceptible species occurring in the skin folds, in the sweat zone areas, axillae and inframmary folds:

1. Dermatophyte infections including Tinea Corporis, Tinea Cruris, Tinea Pedis (Athlete's Foot)
2. Cutaneous Candidiasis
3. Fungal diper dermatitis

4.2 Posology and method of administration

The affected area should be washed with soap and water and dried thoroughly. Candid Powder should be sprinkled onto the affected area(s) twice daily, morning and evening, in both adults and children (2-12 years of age). Clotrimazole powder can also be dusted into clothes or shoes in contact with the affected area. It can be used to help prevent the infection returning, particularly in skin folds or areas where sweating is a problem, as fungal infections often thrive in these environments.
Children should be supervised during the use of Candid Powder. Clotrimazole powder can be used in addition to either cream or spray. The duration of therapy varies with type of infection and extent of the disease however, treatment of cutaneous candidiasis and most dermatophyte infections usually requires 3 to 4 weeks.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Do not use this product to treat nail or scalp infections.

4.4 Special warnings and precautions for use

None Known

4.5 Interaction with other medicinal products 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 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. 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

Topical clotrimazole 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.

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.

Reporting of suspected adverse reactions

Reporting suspected adverse reaction after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

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 Pharmacodynamics properties

Pharmacotherapeutic group: Antifungals for topical use – imidazole and triazole derivatives
ATC Code: D01A C01

Mechanism of Action
Clotrimazole acts against fungi by inhibiting ergosterol synthesis. Inhibition of ergosterol synthesis leads to structural and functional impairment of the 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 µg/ml, suggesting that clotrimazole applied topically is unlikely to lead to measurable systemic effects or side effects.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on studies of repeated dose toxicity, genotoxicity and carcinogenicity.

Clotrimazole was not teratogenic in reproductive toxicity studies in mice, rats and rabbits. In rats high oral doses were associated with maternal toxicity, embryotoxicity, reduced fetal weights and decreased pup survival.

In rats clotrimazole and/or its metabolites were secreted into milk at levels higher than in plasma by a factor of 10 to 20 at 4 hrs after administration, followed by a decline to a factor of 0.4 by 24 hrs.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize starch, Colloidal Silicon Dioxide, Powder Perfume
,7238, Purified talc.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

48 Months

6.4 Special precautions for storage

Store below 30°C. Protect from light.

6.5 Nature and contents of container <and special equipment for use, administration or implantation>

A printed sleeved plastic bottle fitted with plug and blue coloured cap containing a fine white to pale yellow powder with pleasant odour. Pack size: 30 gm, 100 gm

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

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8. MANUFACTURER

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9. NAFDAC REGISTRATION NUMBER(S)

NAFDAC Reg No.: 04-6760