SUMMARY OF PRODUCT CHARACTERISTICS

Candid Mouth Paint

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1. NAME OF THE MEDICINAL PRODUCT

Candid Mouth Paint

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

COMPOSITION

Clotrimazole USP 1% w/v

Excipients: Propylene Glycol USP, Glycerol BP

3. PHARMACEUTICAL FORM

Mouth Paint (Solution for oral thrush)

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Candid Mouth Paint is indicated for the local treatment of oropharyngeal candidiasis.

4.2. Posology and Method of Administration

Children (above 3yrs) and Adults -10-20 drops (0.5-1ml) gently applied in mouth 3-4 times daily with cotton bud.

Only limited data are available on the safety and effectiveness of the clotrimazole after prolonged administration; therefore, therapy should be limited to short term use, if possible.

4.3. Contraindications

Candid Mouth Paint is contraindicated in patients who are hypersensitive to any of its components.

4.4. Special Warnings and Precautions for Use

Candid Mouth Paint is not indicated for the treatment of systemic mycoses including systemic candidiasis.

Abnormal liver function tests have been reported in patients treated with clotrimazole; elevated SGOT levels were reported in about 15% of patients in the clinical trials. In most cases the elevations were minimal and it was often impossible to distinguish effects of clotrimazole from those of other therapy and the underlying disease (malignancy in most cases). Periodic assessment of hepatic function is advisable particularly in patients with pre-existing hepatic impairment.

4.5. Interaction with other medicinal products and other forms of interaction

No data are available.

4.6. Fertility, pregnancy and lactation

Pregnancy

Pregnancy Category C:
Clotrimazole has been shown to be embryotoxic in rats and mice when given in doses 100 times the adult human dose (in mg/kg), possibly secondary to maternal toxicity. The drug was not teratogenic in mice, rabbits, and rats when given in doses up to 200, 180, and 100 times the human dose.

Clotrimazole given orally to mice from nine weeks before mating through weaning at a dose 120 times the human dose was associated with impairment of mating, decreased number of viable young, and decreased survival to weaning. No effects were observed at 60 times the human dose. When the drug was given to rats during a similar time period at 50 times the human dose, there was a slight decrease in the number of pups per litter and decreased pup viability.

There are no adequate and well controlled studies in pregnant women. Candid Mouth Paint should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

4.7. Effects on ability to drive and use machines
No data are available.

4.8. Undesirable effects
Abnormal liver function tests have been reported in patients treated with clotrimazole lozenges; elevated SGOT levels were reported in about 15% of patients in the clinical trials.

Nausea, vomiting, unpleasant mouth sensations and pruritus have also been reported with the use of the lozenge.

4.9. Overdose
No data are available.

5. PHARMACOLOGICAL PROPERTIES
5.1. Pharmacodynamic properties
Mechanism of action
Clotrimazole is a broad-spectrum antifungal agent that inhibits the growth of pathogenic yeasts by altering the permeability of cell membranes. The action of clotrimazole is fungistatic at concentrations of drug up to 20 mcg/mL and may be fungicidal *in vitro* against *Candida albicans* and other species of the genus *Candida* at higher concentrations. No single-step or multiple-step resistance to clotrimazole has developed during successive passages of *Candida albicans* in the laboratory; however, individual organism tolerance has been observed during successive passages in the laboratory. Such *in vitro* tolerance has resolved once the organism has been removed from the antifungal environment.

Special population

Pediatric Use

Safety and effectiveness of clotrimazole in children below the age of 3 years have not been established; therefore, its use in such patients is not recommended.

The safety and efficacy of the prophylactic use of Candid Mouth Paint in children have not been established.

Geriatric Use

Clinical studies of clotrimazole did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients.

5.2. Pharmacokinetic properties

After oral administration of a 10 mg clotrimazole lozenge to healthy volunteers, concentrations sufficient to inhibit most species of *Candida* persist in saliva for up to three hours following the approximately 30 minutes needed for a lozenge to dissolve. The long term persistence of drug in saliva appears to be related to the slow release of clotrimazole from the oral mucosa to which the drug is apparently bound. Repetitive dosing at three hour intervals maintains salivary levels above the minimum inhibitory concentrations of most strains of Candida; however, the relationship between *in vitro* susceptibility of pathogenic fungi to clotrimazole and prophylaxis or cure of infections in humans has not been established.

In another study, the mean serum concentrations were 4.98 ± 3.7 and 3.23 ± 1.4 nanograms/mL of clotrimazole at 30 and 60 minutes, respectively, after administration as a lozenge.

5.3. Preclinical safety data

Carcinogenesis

An 18 month dosing study with clotrimazole in rats has not revealed any carcinogenic effect.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene Glycol and Glycerol

6.2 Incompatibilities

None

6.3 Shelf life

24 Months

6.4 Special precautions for storage

Store below 30°C. Protect from light.

6.5 Nature and contents of container

A printed carton containing a leaflet and a set of temper proof LDPE labelled bottle fitted with a plug and red colored HDPE cap containing a clear colourless viscous liquid.

6.6 Special precautions for disposal and other handling

No special requirements

7. MARKETING AUTHORISATION HOLDER

Registered Office: Glenmark Pharmaceuticals Limited
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8. MARKETING AUTHORISATION NUMBER(S)

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9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10. DATE OF REVISION OF THE TEXT

May 2020