

SUMMARY OF PRODUCT CHARACTERISTICS

Candid Mouth Paint 1% w/v (Clotrimazole 1% w/v)

1. NAME OF THE MEDICINAL PRODUCT

Candid Mouth Paint (Clotrimazole 1% w/v)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Clotrimazole USP 1% w/v

Non aqueous base.....Q.S.

For excipients see section 6.1.

3. PHARMACEUTICAL FORM

Solution for Oral Cavity

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Candid Mouth Paint (Clotrimazole 1% w/v) is indicated for the treatment of oral 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

Warning

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

Precautions

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.

Paediatric 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 clotrimazole 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.

4.5 Interaction with other medicinal products and other forms of interaction

No information is available on drug interactions, as systemic absorption is minimal, drug interactions are unlikely.

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 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 clotrimazole lozenge.

Reporting suspected adverse reactions

Reporting suspected adverse reactions after Authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Pharmacovigilance Electronic Reporting System (PvERS) <https://pv.pharmacyboardkenya.org/>

4.9 Overdose

No data available.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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.

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

Glycerol, Propylene glycol

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 Months

6.4 Special precautions for storage

Store below 30°C. Protected from light.

6.5 Nature and contents of container

A printed carton containing a leaflet and a labelled LDPE bottle fitted with a plug and red coloured cap.

6.6 Special precautions for disposal and other handling

Keep all Medicines out of reach of Children.

7. MARKETING AUTHORISATION HOLDER

Glenmark Pharmaceuticals Limited,
B/2, Mahalaxmi Chambers, 22 Bhulabhai Desai
Road, Mumbai, 400 026, India

8. MARKETING AUTHORISATION NUMBER(S)

5792/R1

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

2026 July 14

10. DATE OF REVISION OF THE TEXT

25/08/2026