

SAME SIZE ARTWORK  
LEAFLET SIZE: 130 mm x 100 mm

33 mm

25 mm

25 mm

**INSTRUCTIONS FOR USE**

1)  **SPIKE**  
Tighten the cap on the nozzle

2)  The spike in the cap will pierce the tip of the vial.

3)  Dispense drops with gentle pressure. Close the cap properly after every use.

SPACE FOR PHARMACODE:

MAL19910861XZ  
Date of Revision: 9 August 2021

**Product Registration Holder**  
Glenmark Pharmaceuticals (Malaysia) Sdn Bhd (660397-W)  
D-31-02, Menara Suezcap 1,  
No. 2, Jalan Kerinchi,  
59200 Kuala Lumpur, Malaysia  
Manufactured by :  
**glenmark**  
**PHARMACEUTICALS LTD.**  
Plot No. E-37, 39, D-Road,  
MIDC, Satpur, Nashik - 422 007,  
Maharashtra State, India.  
™ Trade Mark

PE000000 MY

*For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory*

**candid**™  
**Mouth Paint 1%**

**COMPOSITION**  
Clotrimazole USP 1%  
in Propylene Glycol USP  
and Glycerin BP base q.s.

**PRODUCT DESCRIPTION**  
A clear colourless viscous liquid.

**THERAPEUTIC CLASS**  
T0130

**PHARMACOLOGY**  
**Mechanism of action**  
Clotrimazole is an imidazole antifungal agent and is effective against a wide variety of fungi including Epidermophyton, Microsporum, and Trichophyton spp., Coccidioides immitis, Histoplasma capsulatum, aspergillus and Candida spp. Other fungi responding to Clotrimazole include Cryptococcus neoformans, Malassezia furfur, Paracoccidioides brasiliensis, Sporothrix schenckii, Pseudallescheria, Medurella and Phialophora spp.

Clotrimazole also has antibacterial action and some strains of Staphylococcus aureus and Streptococcus pyogenes have been reported to be sensitive.

Clotrimazole is believed to exert its activity on the cell membrane of the fungus. Its appears that the drug inhibits protein synthesis and so influences the utilisation and the incorporation of the acylated amino acids essential for fungi.

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**Pharmacokinetics**  
Clotrimazole appears to be well absorbed in humans following oral administration and is eliminated mainly as inactive metabolites. Following topical and vaginal administration, however, Clotrimazole appears to be minimally absorbed. Six hours after the application of radioactive Clotrimazole 1% cream and 1% solution onto intact and acutely inflamed skin, the concentration of Clotrimazole varied from 100 mcg / cm<sup>2</sup> in the stratum corneum to 0.5 to 1 mcg / cm<sup>2</sup> in the stratum reticulare, and 0.1 mcg / cm<sup>2</sup> in the subcutis. No measurable amount of radioactivity ( < 0.001 mcg/ml ) was found in the serum within 48 hours after application under occlusive dressing of 0.5 ml of the solution or 0.8 g of the cream. Only 0.5% or less of the applied radioactivity was excreted in the urine.

**INDICATIONS**  
Oral Thrush (Monilial Thrush).

**CONTRAINDICATIONS**  
Except for possible hypersensitivity reactions, there are no contraindications for CANDID Mouth Paint.

**SIDE EFFECTS / ADVERSE REACTIONS**  
Except for rare cases of hypersensitivity, no side-effects are reported.

**PRECAUTIONS / WARNINGS**  
For irritation or sensitivity caused with the use of Clotrimazole; treatment should be discontinued and appropriate therapy instituted. The patient should be advised to use the medication for the full treatment time even though the symptoms may have improved.

**DRUG INTERACTION**  
No kind of drug interactions have been reported.

**USE IN PREGNANCY AND LACTATION**  
*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.

There are no adequate and well controlled studies in pregnant women.

**Lactation**  
It is not known whether this drug is excreted in human milk, caution should be exercised when Clotrimazole is used by a nursing mother.

**RECOMMENDED DOSAGE, DOSAGE SCHEDULE AND ROUTE OF ADMINISTRATION**  
10 - 20 drops ( 1/2 to 1 ml ) of CANDID Mouth Paint are gently applied in the mouth, 3 to 4 times daily, preferably with the help of a cotton bud. Care should be taken to ensure that all the lesions in the mouth are covered. Although improvement is seen in 3 to 5 days generally, treatment should be continued till the infection is completely eliminated. Attention should be directed to the control of any factor that may predispose the patient to infection as this will help prevent recurrence.

**SYMPTOMS AND TREATMENT FOR OVERDOSAGE AND ANTIDOTE (S)**  
Acute overdose with topical application of Clotrimazole is unlikely and it is not expected to represent a life-threatening situation.

**PACKING / PACK SIZES**  
15 ml LDPE Bottle


**SHELF LIFE**  
24 Months

**STORAGE CONDITIONS, USER INSTRUCTIONS AND PHARMACEUTICAL PRECAUTIONS**  
Store below 30°C. Protect from light.

PE000000 MY

ICONGRAPHICS CODE:

PANTONE SHADE



PANTONE  
BLACK  
PROCESS C

Supersedes  
Artwork Code:

PHARMACODE: