

SUMMARY OF PRODUCT CHARACTERISTICS

Candid Mouth Paint

1. NAME OF THE MEDICINAL PRODUCT

Candid (Clotrimazole Mouth Paint 1% w/v)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

lotrimazole USP 1% w/v

Propylene Glycol USP, Glycerol BP base q.s.

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

Glycerol and Propylene Glycol.

6.2. Incompatibilities

Not applicable

6.3. Shelf life

24 months

6.4. Special precautions for storage

Do not store above 30°C. Protect from light.

6.5. Nature and contents of container

A printed carton containing a leaflet and a labeled LDPE bottle fitted with a plug and red coloured cap containing a clear colourless viscous liquid.

6.6. Special precautions for disposal and other handling

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

7. MARKETING AUTHORISATION HOLDER

Glenmark Pharmaceuticals Limited
B/2, Mahalaxmi Chambers,
22, Bhulabhai Desai road, Mumbai – 400 026

8. MARKETING AUTHORISATION NUMBER(S)

FDA/SD.203-04166

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

01.11.2003

10. DATE OF REVISION OF THE TEXT

May 20

PACKAGE LEAFLET – INFORMATION FOR THE USER

Candid Mouth Paint

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to you doctor or pharmacist. This includes any possible side effects not listed in the leaflet.

What is in this leaflet:

1. What Candid Mouth Paint is and what it is used for
2. What you need to know before you use Candid Mouth Paint
3. How to use Candid Mouth Paint
4. Possible side effects
5. How to store Candid Mouth Paint
6. Contents of the pack and other Information.

1. What Candid Mouth Paint is and what it is used for

Candid Mouth Paint is a trade name for the antifungal medicine, Clotrimazole. Candid Mouth Paint is used to treat infections in or around the mouth, throat or tongue caused by yeast-like fungi called *Candida*. This condition is known as oral candidiasis or thrush. *Candida albicans* is the most common cause of thrush.

C. albicans is present in the gut of both men and women, and often in women's vaginas without causing problems. When conditions are suitable for its growth, *C. albicans* will multiply and cause infection.

A number of different conditions provide favourable growth conditions for *Candida*.

Ask your doctor if you have any questions about why Candid Mouth Paint has been prescribed for you.

2. What you need to know before you use Candid Mouth Paint

Do not use Candid Mouth Paint:

- if you have an allergy to it or to any ingredients in the formulation listed at the end of this leaflet.
- to treat fungal infections affecting internal organs.
- in children below the age of 3 years.

Warnings and precautions:

- before taking this medication, tell your doctor if you have liver disease. You may not be able to take clotrimazole, or special monitoring during treatment.
- allow the paint to dissolve slowly in the mouth in order to achieve maximum effect of the medication

Other medicines and Candid Mouth Paint

Tell your pharmacist if you are taking other medicines, including vitamin and herbal supplements or any medicines you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may affect the way others work. Your doctor or pharmacist may have more information on medicines to be careful with or to avoid while using Candid Mouth Paint.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you might be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Candid Mouth Paint should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Driving and using machines

This medicine is not expected to affect your ability to drive or use machines.

3. How to use Candid Mouth Paint

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

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

If you wear dentures, take them out while applying Candid Mouth Paint. This allows the medicine to reach where the dentures normally fit. Before replacing your dentures, clean them thoroughly.

If you take more Candid Mouth Paint

Talk to a doctor or go to your nearest hospital casualty department straight away. Take your medicine and this leaflet with you. Symptoms of a clotrimazole overdose are unknown.

If you forget to Candid Mouth Paint

Apply the Candid Mouth Paint as soon as possible and then continue the rest of your treatment as usual. Do not take a double dose to make up for the missed dose. If you are not sure what to do, ask your pharmacist.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

While using Candid Mouth Paint

Things you must do

If you are about to start taking any new medicines, tell all doctors and pharmacists who are treating you that you are using Candid Mouth Paint.

If you become pregnant while using Candid Mouth Paint, tell your doctor immediately.

If you plan to have surgery, tell your doctor or dentist that you are using Candid Mouth Paint.

If your symptoms do not improve while you are using Candid Mouth Paint or they become worse, tell your doctor.

Things you must not do

Do not give Candid Mouth Paint to anyone else, even if they have the same condition as you. Candid Mouth Paint is intended for mouth infections only, caused by Candida yeast infections.

Do not use

Candid Mouth Paint to treat any other complaints unless your doctor or pharmacist tells you to.

Unless you experience a bad side effect or allergic reaction to Candid Mouth Paint, do not stop using Candid Mouth Paint until the infection is cured.

Things that may help your condition

To avoid the possibility of re-infection or infection of other household members, you must observe strict personal hygiene. Hands must be washed thoroughly before and after using Candid Mouth Paint.

Wash used kitchen utensils by boiling for 20 minutes. Wash your used utensils separately and keep them away from utensils used by other household members. This may help prevent spread of the infection.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

After you apply Candid Mouth Paint you might experience:

- abnormal liver function tests
- nausea or stomach upset,
- vomiting,
- itching, or
- an unpleasant sensation in the mouth.

Side effects other than those listed here may also occur. Talk to your doctor about any side effect that seems unusual or that is especially bothersome.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Candid Mouth Paint

Don not store above 30°C. Protect from light.

6. Contents of the pack and other information**What Candid Mouth Paint looks like and contents of the pack**

A printed carton containing a leaflet and a labeled LDPE bottle fitted with a plug and red coloured cap containing a clear colourless viscous liquid.

Marketing authorisation holder:

Glenmark Pharmaceuticals Limited
B/2, Mahalaxmi Chambers,
22, Bhulabhai Desai road, Mumbai – 400 026

Manufacturer:

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