SUMMARY OF PRODUCT CHARACTERISTICS
Candid (Clotrimazole 1% w/v Lotion)

1. NAME OF THE MEDICINAL PRODUCT

Candid (Clotrimazole 1% w/v Lotion)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Clotrimazole USP 1% w/v

Non aqueous base

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Topical Lotion

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Prescription Clotrimazole Lotion product is indicated for the topical treatment of candidiasis due to *Candida albicans*, and tinea versicolor due to *Malassezia furfur*.

This formulation is also available as a nonprescription product which is indicated for the topical treatment of the following dermal infections: tinea pedis, tinea cruris, and tinea corporis due to *Trichophyton rubrum, Trichophyton mentagrophytes, Epidermophyton fluoccosum,* and *Microsporum canis*.

4.2. Posology and Method of Administration

Gently massage sufficient Clotrimazole Lotion into the affected and surrounding skin areas twice a day, in the morning and evening.

Clinical improvement, with relief of pruritus, usually occurs within the first week of treatment with Clotrimazole Lotion. If the patient shows no clinical improvement after 4 weeks of treatment with Clotrimazole Lotion, the diagnosis should be reviewed.

4.3. Contraindications

Topical antifungal agents are contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation.

4.4. Special Warnings and Precautions for Use

For External application only.

WARNINGS

Clotrimazole Lotion is not for ophthalmic use.

PRECAUTIONS

General

If irritation or sensitivity develops with the use of clotrimazole, treatment should be discontinued and appropriate therapy instituted.

Information for Patients

This information is intended to aid in the safe and effective use of this medication. It is not a disclosure of all possible adverse or intended effects.

The patient should be advised to:

1. Use the medication for the full treatment time even though the symptoms may have improved. Notify the physician if there is no improvement after 4 weeks of treatment.
2. Inform the physician if the area of application shows signs of increased irritation (redness, itching, burning, blistering, swelling, oozing) indicative of possible sensitization.
3. Avoid sources of infection or reinfection.

Laboratory Tests

If there is lack of response to Clotrimazole, appropriate microbiological studies should be repeated to confirm the diagnosis and rule out other pathogens before instituting another course of antimycotic therapy.

Pediatric Use

Safety and effectiveness in pediatric patients have been established for clotrimazole when used as indicated and in the recommended dosage.

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

Synergism or antagonism between clotrimazole and nystatin, or amphotericin B, or flucytosine against strains of *C. albicans* has not been reported.

4.6. Pregnancy and lactation

Pregnancy

Pregnancy Category B

The disposition of ^{14}C-clotrimazole has been studied in humans and animals. Clotrimazole is very poorly absorbed following dermal application or intravaginal administration to humans.

In clinical trials, use of vaginally applied clotrimazole in pregnant women in their second and third trimesters has not been associated with ill effects.

There are, however, no adequate and well-controlled studies in pregnant women during the first trimester of pregnancy.

Studies in pregnant rats with intravaginal doses up to 100 mg/kg have revealed no evidence of harm to the fetus due to clotrimazole.

High oral doses of clotrimazole in rats and mice ranging from 50 to 120 mg/kg resulted in embryotoxicity (possibly secondary to maternal toxicity), impairment of mating, decreased litter size and number of viable young and decreased pup survival to weaning. However, clotrimazole was not teratogenic in mice, rabbits and rats at oral doses up to 200, 180 and 100 mg/kg, respectively. Oral absorption in the rat amounts to approximately 90% of the administered dose.

Because animal reproduction studies are not always predictive of human response, this drug should be used only if clearly indicated during the first trimester of pregnancy.

Nursing Mothers

It is not known whether this drug is excreted in human milk, caution should be exercised when clotrimazole is used by a nursing woman.

4.7. Effects on ability to drive and use machines

Clotrimazole has no or negligible influence on the ability to drive or use machines.

4.8. Undesirable effects

The following adverse reactions have been reported in connection with the use of Clotrimazole: erythema, stinging, blistering, peeling, edema, pruritus, urticaria, burning, contact dermatitis and general irritation of the skin.

Reporting of 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.

4.9. Overdose

Acute overdosage with topical application of clotrimazole is unlikely and would not be expected to lead to a life-threatening situation.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Antifungals for topical use – imidazole and triazole derivatives

ATC Code: D01A C01

Clotrimazole is a broad-spectrum antifungal agent that is used for the treatment of dermal infections caused by various species of pathogenic dermatophytes, yeasts, and *Malassezia furfur*. The primary action of clotrimazole is against dividing and growing organisms.

In vitro, clotrimazole exhibits fungistatic and fungicidal activity against isolates of *Trichophyton rubrum*, *Trichophyton mentagrophytes*, *Epidermophyton floccosum*, *Microsporum canis* and *Candida species* including *Candida albicans*. In general, the *in vitro* activity of clotrimazole corresponds to that of tolnaftate and griseofulvin against the mycelia of dermatophytes (*Trichophyton, Microsporum,* and *Epidermophyton*), and to that of the polyenes (amphotericin B and nystatin) against budding fungi (*Candida*). Using an *in vivo* (mouse) and an *in vitro* (mouse kidney homogenate) testing system, clotrimazole and miconazole were equally effective in preventing the growth of the pseudomycelia and mycelia of *Candida albicans*.

Strains of fungi having a natural resistance to clotrimazole are rare. Only a single isolate of *Candida guilliermondi* has been reported to have primary resistance to clotrimazole.

No single-step or multiple-step resistance to clotrimazole has developed during successive passages of *Candida albicans* and *Trichophyton mentagrophytes*. No appreciable change in sensitivity was detected after successive passage of isolates of *C. albicans*, *C. krusei*, or *C. pseudotropicalis* in liquid or solid media containing clotrimazole. Also, resistance could not be developed in chemically induced mutant strains of polyene-resistant isolates of *C. albicans*.

Slight, reversible resistance was noted in three isolates of *C. albicans* tested by one investigator. There is a single report that records the clinical emergence of *C. albicans* strain with considerable resistance to flucytosine and miconazole, and with cross-resistance to clotrimazole, the strain remained sensitive to nystatin and amphotericin B.

In studies of the mechanism of action, the minimum fungicidal concentration of clotrimazole caused leakage of intracellular phosphorus compounds into the ambient medium with concomitant breakdown of cellular nucleic acids and accelerated potassium efflux. Both these events began rapidly and extensively after addition of the drug.

5.2. Pharmacokinetic properties

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 $\mu g/cm^3$ in the stratum corneum to 0.5 to 1 $\mu g/cm^3$ in the stratum reticulare, and 0.1 $\mu g/cm^3$- in the subcutis.

No measurable amount of radioactivity ($\leq$0.001 µg/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.

Following intravaginal administration of 100 mg ^{14}C-clotrimazole vaginal tablets to nine adult females, an average peak serum level, corresponding to only 0.03 µg equivalents/mL of clotrimazole, was reached one to two days after application. After intravaginal administration of 5 g of 1% ^{14}C-Clotrimazole vaginal Cream containing 50 mg active drug, to five subjects (one with candidal colpitis), serum levels corresponding to approximately 0.01 µg equivalents/mL were reached between 8 and 24 hours after application.

5.3. Preclinical safety data

Carcinogenicity

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

Mutagenicity

In tests for mutagenesis, chromosomes of the spermatophores of Chinese hamsters which had been exposed to clotrimazole were examined for structural changes during the metaphase.

Prior to testing, the hamsters had received five oral clotrimazole doses of 100 mg/kg body weight. The results of this study showed that clotrimazole had no mutagenic effect.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Propylene Glycol

6.2. Incompatibilities

Not Applicable

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 an insert and a labeled LDPE bottle fitted with a plug and cream coloured cap containing 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.203-04165

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

12.09.2003

10. DATE OF REVISION OF THE TEXT

Nov 2019

INFORMATION FOR THE PATIENTS
Candid (Clotrimazole) 1% Lotion

Read all of this leaflet carefully because it contains important information for you.
This medicine is available without prescription. However, you still need to use Candid Lotion carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.
- If you have any unusual effects after using this product, tell your doctor or pharmacist.

IN THIS LEAFLET

1. WHAT IS CANDID LOTION AND WHAT IS IT USED FOR?

Candid Lotion is used to treat fungal skin infections i.e. for the topical treatment of candidiasis (Disease caused by the yeast) due to *Candida albicans* and tinea versicolor (fungus infection) due to *Malassezia furfur*. Also it is used for the topical treatment of the following dermal infections: tinea pedis (common skin infection of the feet- Athlete's foot), tinea cruris (superficial fungus infection of the crotch and perineum), and tinea corporis (superficial fungal infection (dermatophytosis) of the arms and legs, especially on glabrous skin) due to *Trichophyton rubrum, Trichophyton mentagrophytes, Epidermophyton fluoccosum,* and *Microsporum canis*.

If you are unsure whether you have one of these fungal skin infections, seek the advice of your doctor or pharmacist.

The active substance in Candid Lotion is clotrimazole. Clotrimazole belongs to a group of medicines called imidazoles and is an antifungal agent which fights the cause of fungal skin infections.

2. BEFORE YOU USE CANDID LOTION

Do not use Candid Lotion:

- If you are allergic (hypersensitive) to clotrimazole or the other ingredients of Candid Lotion.

Using other medicines:

Synergism or antagonism between clotrimazole and nystatin, or amphotericin B, or flucytosine against strains of *C. albicans* has not been reported. Consult your doctor before using these products together.

Pregnancy and breast-feeding:

If you are pregnant, breast-feeding or trying for a baby, tell your doctor or midwife before using Candid Lotion. If you have informed your doctor or midwife already, follow his/her instructions carefully.

3. HOW TO USE CANDID LOTION?

FOR TOPICAL USE ONLY.

NOT FOR OPTHALMIC USE.

If irritation or sensitivity develops with the use of clotrimazole, treatment should be discontinued and appropriate therapy instituted.

If Candid Lotion has been prescribed for you by your doctor, follow any instructions he/she may have given you. If you purchased this product without a prescription, follow these directions closely:

- Gently massage sufficient Clotrimazole Lotion into the affected and surrounding skin areas twice a day, in the morning and evening.
- If no clinical improvement after 4 weeks of treatment with Clotrimazole Lotion, the diagnosis should be reviewed.
- Use the medication for the full treatment time even though the symptoms may have improved. Notify the physician if there is no improvement after 4 weeks of treatment.
- Inform the physician if the area of application shows signs of increased irritation (redness, itching, burning, blistering, swelling, oozing) indicative of possible sensitization.
- Avoid sources of infection or reinfection

Do not put the lotion in your mouth or swallow it.

If the lotion is swallowed accidentally, tell your doctor straight.

If you accidentally get lotion in your eyes or mouth, wash immediately with water and contact your doctor.

If you forget to use Candid Lotion:

Apply the lotion as soon as possible and then continue the rest of your treatment as usual.

You can help the treatment to work if you follow these simple self-help tips:

- Although the infected area will itch, try not to scratch. Scratching will damage the surface of the skin and cause the infection to spread further.
- Keep the affected skin areas clean.
- Pay particular attention to drying the skin, but avoid excessive rubbing.
- Do not share towels, bath mats, etc. with other people as you could spread the infection to them.
- Always wash your hands after treating the infection to prevent it from spreading.
-

If you have tinea pedis (athlete's foot):

- Remember to dry the skin between the toes thoroughly.
- Wash your socks, stockings and tights thoroughly in hot water to remove any shed skin or fungal spores.
- Change your footwear daily if possible.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Candid Lotion can cause side effects, although not everybody gets them.

As with all medicines, some people may be allergic to the lotion. If you are allergic, a reaction will occur soon after you start using it. If you experience an allergic reaction, stop using Candid Lotion and tell your doctor straight away.

After you apply the lotion you might experience:

- erythema (redness of the skin),
- stinging (burning sensation),
- blistering (collection of fluid underneath the top layer of skin),
- peeling,
- edema (swelling of soft tissues as a result of excess fluid accumulation),
- pruritius (severe itching of the skin),
- urticaria (itchy areas of skin- sign of an allergic reaction),
- burning, and
- general irritation of the skin.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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 LOTION?

Keep out of the reach and sight of children.

This product should be stored in the original carton.

Store below 30°C. Protect from light.

Do not use Candid Lotion after the expiry date.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Candid Lotion contains?

Active Ingredient: Clotrimazole USP 1% w/w.

Inactive Ingredients: Propylene Glycol

What Candid Lotion looks like and contents of the pack:

Candid Lotion is available in bottles containing 20 ml clear colourless solution.

Marketing Authorisation Holder:

Glenmark Pharmaceuticals Ltd
B/2, Mahalaxmi Chambers,
22, Bhulabhai Desai Road,
Mumbai – 400026 (India)

Manufactured by:

Glenmark Pharmaceuticals Ltd
At: Plot No. E-37, 39, MIDC Area,
Satpur, Nashik - 422007,
Maharashtra India

Remember: If you have any doubts about using Candid Lotion correctly, seek the advice of your doctor or pharmacist.

This leaflet was last revised in Nov 2019.