

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Candid (Clotrimazole 1% w/w) Dusting Powder

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Clotrimazole USP	1% w/w
Purified Talc base	q.s

For excipient list, refer section 6.1

3. PHARMACEUTICAL FORM

Powder for topical application

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Candid Dusting Powder should be used externally as an adjunct to treatment with Clotrimazole Cream, Solution or Dermatological Spray and as a prophylactic against reinfection, particularly in infections involving skin folds, and where perspiration is a problem.

4.2. Posology and Method of Administration

Candid Dusting Powder should be sprinkled onto the affected areas two to three times daily after using Clotrimazole Cream, Solution or Dermatological Spray. The powder may also be dusted inside articles of clothing and footwear which are in contact with the infected area.

4.3. Contraindications

Hypersensitivity to clotrimazole or the excipients

4.4. Special Warnings and Precautions for Use

None

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

None

4.6. Pregnancy and lactation

Data on a large number of exposed pregnancies indicate no adverse effects of clotrimazole on pregnancy or on the health of the foetus/newborn child. To date, no relevant epidemiological data are available.

Clotrimazole can be used during pregnancy, but only under the supervision of a physician or midwife.

4.7. Effects on ability to drive and use machines

Not applicable.

4.8. Undesirable effects

Rarely patients may experience local mild burning or irritation immediately after applying the powder. Very rarely the patient may find this irritation intolerable and stop treatment.

Other undesirable effects:

Body as a whole: allergic reaction, pain

Skin and appendages: pruritus, rash

4.9. Overdose

In the event of accidental oral ingestion, routine measures such as gastric lavage should be performed only if clinical symptoms of overdose become apparent (e.g. dizziness, nausea or vomiting). It should be carried out only if the airway can be protected adequately.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

ATC Code: D01A C01

Clotrimazole is an imidazole derivative with a broad spectrum of antimycotic activity. It also exhibits activity against *Trichomonas*, staphylococci, streptococci and *Bacteroides*. It has no effect on lactobacilli.

Mechanism of Action

Clotrimazole acts against fungi by inhibiting ergosterol synthesis. Inhibition of ergosterol synthesis leads to structural and functional impairment of the cytoplasmic membrane.

Pharmacodynamic Effects

Clotrimazole has a broad antimycotic spectrum of action *in vitro* and *in vivo*, which includes dermatophytes, yeasts, moulds, etc.

The mode of action of clotrimazole is fungistatic or fungicidal depending on the concentration of clotrimazole at the site of infection. *In-vitro* activity is limited to proliferating fungal elements; fungal spores are only slightly sensitive.

Primarily resistant variants of sensitive fungal species are very rare; the development of secondary resistance by sensitive fungi has so far only been observed in very isolated cases under therapeutic conditions.

5.2. Pharmacokinetic properties

Pharmacokinetic investigations after dermal application have shown that clotrimazole is practically not absorbed from the intact or inflamed skin into the human blood

circulation. The resulting peak serum concentrations of clotrimazole were below the detection limit of 0.001 µg/ml, reflecting that clotrimazole applied topically does not lead to measurable systemic effects or side effects.

5.3. Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to those already included in other sections of the Summary of Product Characteristics.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Inactive material are Maize starch, Colloidal Silicon Dioxide, Powder Perfume 7238, and Purified talc.

6.2. Incompatibilities

Not applicable

6.3. Shelf life

48 months

6.4. Special precautions for storage

Store below 30°C. Protect from light.

6.5. Nature and contents of container

A printed plastic bottle fitted with plug and blue coloured cap.

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.203-04162

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

01.11.2003

10. DATE OF REVISION OF THE TEXT

Nov 2017

PATIENT INFORMATION LEAFLET

Candid Dusting Powder

Clotrimazole 1% w/w

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 Dusting Powder 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 Dusting Powder and what is it used for?
2. Before you use Candid Dusting Powder
3. How to use Candid Dusting Powder
4. Possible side effects
5. How to store Candid Dusting Powder
6. Further information

1. WHAT IS CANDID DUSTING POWDER AND WHAT IS IT USED FOR?

Candid Dusting Powder is used along with clotrimazole cream or clotrimazole dermatological spray to treat fungal skin infections, particularly athlete's foot. It is also used alone to help prevent re-infection.

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 Dusting Powder 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 DUSTING POWDER

Do not use Candid Dusting Powder:

If you are allergic (hypersensitive) to clotrimazole or the other ingredient of Candid Dusting Powder, maize starch.

Using other medicines:

The powder should be used along with clotrimazole cream or clotrimazole dermatological spray to treat fungal skin infections or alone to help prevent re-infection.

Pregnancy and breast-feeding:

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

3. HOW TO USE CANDID DUSTING POWDER

If Candid Dusting Powder 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:

- If the feet are infected, they should be washed and dried thoroughly, especially between the toes, before applying the powder.
- Candid Dusting Powder should be sprinkled onto the affected areas two or three times daily, after using clotrimazole cream or clotrimazole dermatological spray.
- The powder may also be dusted inside articles of clothing and footwear which are in contact with the affected areas. If the socks are being dusted, it should be done by turning them inside out and applying the powder directly to the area that will be in contact with the affected part of the foot.

The symptoms of skin infection, such as itching or soreness, should improve within a few days of treatment although signs such as redness and scaling may take longer to disappear. If symptoms persist, consult your doctor.

Candid Dusting Powder is for external use only:

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

If the powder is swallowed accidentally, tell your doctor straight away or contact the Accident and Emergency Department of your nearest hospital.

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

If you forget to use Candid Dusting Powder:

Apply the powder 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 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

As with all medicines, some people may be allergic to the powder. If you are allergic, a reaction will occur soon after you start using it. If you experience an allergic reaction, stop using Candid Dusting Powder and tell your doctor straight away or contact the Accident and Emergency Department of your nearest hospital. Signs of an allergic reaction may include:

- Rash.
- Swallowing or breathing problems.
- Swelling of your lips, face, throat or tongue.
- Weakness, feeling dizzy or faint.
- Nausea.

Rarely, immediately after you apply the powder you might experience the following symptoms:

- Mild burning.
- Irritation.

If this is intolerable, stop treatment and see your doctor as soon as possible.

Very rarely, Candid Dusting Powder may cause side effects which can be very similar to the symptoms of the infection. If any of these symptoms gets worse, stop treatment and see your doctor as soon as possible. These symptoms may include:

- Burning, pain or itching.
- Redness.
- Rash.
- Swelling.

If you experience any of the above effects or react badly to the powder in any other way not listed in this leaflet, tell your doctor or pharmacist immediately.

5. HOW TO STORE CANDID DUSTING POWDER

Keep out of the reach and sight of children.

This product should be stored in the original carton.

Store below 25°C; Protect from light.

Do not use Candid Dusting Powder after the expiry date which is stated at one end of the carton and on the label of the pack. The expiry date refers to the last day of that month.

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 Dusting Powder contains:

The active substance is clotrimazole at a strength of 1% w/w.

The other ingredient is Maize starch, Colloidal Silicon Dioxide, Powder perfume 7238, Purified talc .

What Candid Dusting Powder looks like and contents of the pack:

Candid Dusting Powder is available in packs containing 30 g of white powder.

Marketing Authorisation Holder:

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

Manufacturer:

Glenmark Pharmaceuticals Limited
Plot No. E-37,39, D-Road, MIDC, Satpur,
Nashik – 422 007, Maharashtra State, India.

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

Further information about fungal infections:

Fungal infections are very common and affect many people. Some of the most common fungal skin infections include athlete's foot, nappy rash, sweat rash and ringworm.

There are two main types of fungal infection:

- The tinea group, also known as dermatophytes.
- The candida group, also known as yeasts.

The tinea group includes athlete's foot and ringworm, both of which are easily spread by contact. The fungus that causes athlete's foot usually lives harmlessly on our skin and in our environment. The natural balance that normally keeps it under control can be upset by factors such as damp moist conditions. This could happen, for example, through regularly wearing training shoes that keep the feet hot and sweaty. Since this fungus is contagious, it can also often be picked up in changing rooms. Ringworm is usually passed on from animals to children. Ringworm is not actually a worm; its name comes from the circular worm-like shape that it forms on the skin. The main symptom for both is an itchy, scaly and irritating rash.

The candida group can be responsible for conditions such as nappy rash and sweat rash. Sweat rash can appear anywhere on the body, but is more likely to occur where folds of skin

rub against each other, such as: under the breasts, under arms, around the groin and on the back. Candida is a yeast-like fungus that usually lives harmlessly on our skin. However, the natural balance that normally keeps it under control can be upset by factors such as sweating, tight or synthetic clothing and cosmetic preparations such as bath additives. When levels of the yeast increase, the skin can develop the following symptoms: persistent burning and itching, soreness and a variety of patches or blemishes as well as a softened and soggy appearance.

If you have any questions or would like more information, call your pharmacist or doctor for advice.

This leaflet was prepared in May 2017.