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

Fine white to pale yellow powder with a pleasant odour

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