

CANDERM

(Clotrimazole Dusting Powder)

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

CANDERM (Clotrimazole Dusting Powder)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

No	Name	Quantity in kg
1	Clotrimazole USP	8.00
2	Zinc Oxide BP	14.00
3	Micro talc IH	450.00
4	Maize starch BP	320.00
5	Colloidal anhydrous silica BP	1.60
6	Fragrance B 4420 IH	6.00

Definitions:

USP: United State Pharmacopoeia

BP: British Pharmacopoeia

IH: In-house Specification

3. PHARMACEUTICAL FORM

Topical Powder

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Canderm Powder contains Clotrimazole 1% w/w.

Clotrimazole belongs to a group of medicines called imidazoles and is an antifungal agent which fights the cause of long variety of fungal skin infections for example candidiasis caused by *Candida albicans*, Athlete's foot, jock itch, ring worm and pityriasis. Canderm Powder prevents the development of repeated infections. Canderm Powder is useful in heat or friction associated skin rashes that are aggravated by excessive perspiration or moisture.

4.2 Posology and method of administration

Canderm powder should be sprinkled onto the affected areas two or three times daily.

The powder may also be dusted inside articles of clothing and footwear which are in contact with the affected areas. Treatment should be continued for approximately two weeks or as advised by your doctor or pharmacist till disappearance of the symptoms to ensure about a complete cure.

4.3 Contraindications

Do not use Canderm Powder if

You are allergic to Clotrimazole, Zinc Oxide or any of the other ingredients listed in Section 6.

Do not use the powder to treat nail or scalp infections.

Taking other medicines or items

Canderm may affect actions of vaginal contraceptive, condom and diaphragm.

Pregnancy and breast-feeding

Canderm Powder can be used if you are pregnant or breast-feeding under medical supervision.

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4.4 Special warnings and precautions for use

Canderm powder should be sprinkled onto the affected areas two or three times daily.

The powder may also be dusted inside articles of clothing and footwear which are in contact with the affected areas. Treatment should be continued for approximately two weeks or as advised by your doctor or pharmacist till disappearance of the symptoms to ensure about a complete cure.

If you use more amount of Canderm Powder than you should

Contact your health care provider immediately and say exactly how much you have used. Your health care provider will advise you what to do. It is important to contact your health care provider even if you feel well.

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.

4.5 Interaction with other medicinal products and other forms of interaction

Canderm Powder is generally well tolerated.

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.

Other undesirable effects may be: allergic skin reaction, pain, skin itching, rash.

4.6 Pregnancy and lactation

Canderm Powder can be used if you are pregnant or breast-feeding under medical supervision.

4.7 Adverse Reactions

Canderm Powder is generally well tolerated.

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.

Other undesirable effects may be: allergic skin reaction, pain, skin itching, rash.

4.8 Symptoms of Overdosage & Treatment

No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

Pharmacological category: a synthetic, imidazole derivate with broad-spectrum, antifungal activity

6. PHARMACEUTICAL PARTICULARS

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6.1 List of excipients

: Micro Talc BP, Maize Starch BP, Colloidal Anhydrous Silica BP.

6.2 Incompatibilities

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None.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Do not store above 30°C. Protect from sunlight and moisture. Keep out of reach of children.

6.5 Nature and contents of container

Canderm Powder is available in packs containing 50gm and 100gm of powder.

7. MARKETING AUTHORISATION HOLDER

M/s SHALINA HEALTHCARE DMCC

Physical and Postal Address:

30th Floor, Almas Towers,

Jumeirah Lakes Towers Dubai-UAE.

Country: Dubai

8. MARKETING AUTHORISATION IN OTHER COUNTRIES

Registered in Democratic Republic of Ghana, CAR

9. DATE OF FIRST AUTHORISATION

05th October 2016

10. DATE OF UPDATE OF TEXT

May 2022