Summary of Product Characteristics

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1. NAME OF THE MEDICINAL PRODUCT

MYCODERM-C (Clotrimazole Dusting Powder 1% w/w).

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Clotrimazole ……. 1% w/w
Maize Starch …….. q.s
Purified Talc ……..… q.s

3. PHARMACEUTICAL FORM

Topical powder

Description:
White to off-white powder with pleasant perfume.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

MYCODERM-C Dusting Powder is indicated topically in adults and children for the treatment of mycotic/fungal infections (dermatomycoses/ringworm) of the skin.
MYCODERM-C Dusting Powder is also indicated topically as an adjunct therapy in patients receiving other oral or topical antifungal drugs for tinea/ringworm infections.
This therapy is also useful to prevent relapse of mycotic skin infections particularly in areas involving skin-folds (under arms, under breasts, etc.) and where perspiration is usually higher i.e., hyperhidrosis (e.g., armpits, soles of feet, palms of hands, inner thighs, or groin area, etc.).

4.2 Posology and Method of Administration

For topical use on skin in adults and children.
Apply sufficient quantity of powder (thin layer) on the affected areas of the body 2 to 3 times daily. If this product is used for 'athlete's foot' (*Tinea pedis*), feet should be washed and dried properly, especially between the toes, before applying the powder.
Duration of treatment is up to one month depending on the type of infection being treated; to prevent relapse, use this medicine for recommended duration of therapy as suggested by the physician. Do not use for more than 4 weeks without medical advice. Consult physician if symptoms do not improve within 7 days. Do not use this medicine more often than directed.
Or, as directed by Physician.

Method of Administration

- For external use only.
- Follow the directions mentioned on container label.
- Wash hands before and after use.
- Cleanse and dry affected area thoroughly.
- Use/sprinkle enough power (thin layer) to cover the affected area and some of the surrounding skin.

4.3 Contraindications

MYCODERM-C Dusting Powder is contraindicated in patient with known hypersensitivity to the clotrimazole or to any azole antifungal drugs or to any of the excipients listed in section 6.1.

4.4 Special Warnings and Precautions for Use

Do not apply this medication in the eyes, nose, mouth, or vagina.

Severe hypersensitivity reactions, including anaphylaxis and angioedema, have been reported during treatment with other azole topical formulations. If a reaction suggesting hypersensitivity or irritation should occur, the treatment should be discontinued.

Powder must not come into contact with the mucosa of the eyes.

MYCODERM-C Powder contains talc. Avoid inhalation of the powder to prevent irritation of the airways. In particular, when treating infants and children, careful application should be used to prevent inhalation by the child.

4.5 Interaction with Other Medicinal Products and Other Forms of Interaction

Due to the limited systemic availability after topical application, clinically relevant interactions are not reported.

4.6 Fertility, Pregnancy and Lactation

Pregnancy

There is a limited amount of data from the use of clotrimazole in pregnant women. Animal studies with clotrimazole have shown reproductive toxicity at high oral doses. At the low systemic exposures of clotrimazole following topical treatment, harmful effects with respect to reproductive toxicity are not predicted. Clotrimazole can be used during pregnancy under medical supervision.

Breast feeding

There are no data on the excretion of clotrimazole into human milk. However, systemic absorption is minimal after topical administration and is unlikely to lead to systemic effects. Clotrimazole may be used during lactation. If used topically on the nipple area, wash breasts before feeding child.

Fertility

No human studies of the effects of clotrimazole on fertility have been performed. Animal studies have not demonstrated any effects of the drug on fertility.

4.7 Effects on Ability to Drive and Use Machines

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

4.8 Undesirable Effects

System Organ Class	**Effects**
Immune system disorders	Anaphylactic reaction, angioedema, hypersensitivity.
Vascular disorders	Syncope, hypotension.
Respiratory, thoracic and mediastinal disorders	Dyspnoea
Skin and subcutaneous tissue disorders	Blister, dermatitis contact, erythema, paraesthesia,
General disorders and administration site conditions	Application site irritation, application site reaction, oedema, pain.

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. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

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4.9 Overdose
No risk of acute intoxication is seen as it is unlikely to occur following a single dermal application of an overdose (application over a large area under conditions favourable to absorption) or inadvertent oral ingestion. There is no specific antidote.
However, 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). Gastric lavage should be carried out only if the airway can be protected adequately.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic Properties
Pharmacotherapeutic Group: Antifungals for topical use – imidazole and triazole derivatives. **ATC Code:** D01AC01.

Mechanism of Action
Clotrimazole acts against fungi by inhibiting ergosterol synthesis. Inhibition of ergosterol synthesis leads to structural and functional impairment of the fungal cytoplasmic membrane. The mode of action of clotrimazole is primarily fungistatic or fungicidal depending on the concentration of clotrimazole at the site of infection.

Pharmacodynamic Effects
Clotrimazole has a broad antimycotic spectrum of action *in vitro* and *in vivo*, which includes dermatophytes, yeasts, moulds, etc.
Under appropriate test conditions, the MIC values for these types of fungi are in the region of less than 0.062-8.0 µg/ml substrate. *In vitro* activity is limited to proliferating fungal elements; fungal spores are only slightly sensitive.
In addition to its antimycotic action, clotrimazole also acts on gram-positive microorganisms (Streptococci / Staphylococci / Gardnerella vaginalis), and gram-negative microorganisms (Bacteroides). *In vitro* clotrimazole inhibits the multiplication of Corynebacteria and gram-positive cocci - with the exception of Enterococci - in concentrations of 0.5-10 µg/ml substrate.

5.2 Pharmacokinetic Properties
Pharmacokinetic investigations after dermal application have shown that clotrimazole is minimally 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, suggesting that clotrimazole applied topically is unlikely to lead to measurable systemic effects or side effects.

5.3 Preclinical Safety Data

Non-clinical data reveal no special hazard for humans based on studies of repeated dose toxicity, genotoxicity and carcinogenicity.

Clotrimazole was not teratogenic in reproductive toxicity studies in mice, rats and rabbits. In rats high oral doses were associated with maternal toxicity, embryotoxicity, reduced fetal weights and decreased pup survival.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Purified Talc, Maize Starch, Colloidal Anhydrous Silica, Sandal P-4114-A Vital flavour

6.2 Incompatibilities

Not known.

6.3 Shelf-life

36 Months

6.4 Special Precautions for Storage

Store in a dry place below 30^0C and protect from light.

6.5 Nature and Contents of Container

75 gm powder packed in HDPE Container along with pack insert fitted inside the cap.

6.6 Special Precautions for Disposal and Other Handling

The powder should be sprinkled on to the affected areas 2 to 3 times daily. The powder may also be dusted inside articles of clothing and footwear which are in contact with the infected area.

7. MARKETING AUTHORISATION HOLDER

Registered office:
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8. MARKETING AUTHORISATION NUMBER(S)

Certificate No: 06858/08148/NMR/2020

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Nov 28, 2021

10. DATE OF REVISION OF THE TEXT

September 2023.