Summary of Product Characteristics

1. NAME OF THE MEDICINAL PRODUCT

CLOSTAT (Clotrimazole Dusting Powder)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains;
Clotrimazole IP .....1% w/w

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Pharmaceutical form: Powder for topical application
Description: White coloured fine powder. Filled with 75 gm HDPE container

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

This medicinal powder is used in the prevention and treatment of the following symptoms and diseases:

- Fungal infection on vulva
- Fungal infection and skin irritation on Penis
- Fungal infections in groin region
- Fungal irritation and infection in vagina
- Fungal infections on and between toes
- Fungal infections on nappy rashes in children
- Fungal infections skin folds and armpits

4.2 Posology and method of administration

Clostat Dusting Powder should be sprinkled onto the affected areas two to three times daily. 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 excipient rice starch.
- Do not use the powder to treat nail or scalp infections.

4.4 Special warnings and precautions for use

None.

4.5 Interaction with other medicinal products and other forms of interaction

None.

4.6 Fertility, 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.

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: pruritis, rash

Reporting of suspected adverse reactions: Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

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.

5.0 Pharmacological properties

5.1 Pharmacodynamic properties

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.

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

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 available.

6.0 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Talc (Extra White) IP 937.8 mg, Starch IP 50.0 mg, Perfume-Lavender IHS 2.0 mg, Colloidal Silicon Dioxide (Aerosil-200) IP 2.0 mg.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months from the date of manufacture.

6.4 Special precautions for storage

Store below 30 ^{0} C. Protect from light and moisture.

6.5 Nature and contents of container

Filled with 75 gm in HDPE container.

6.6 Special precautions for disposal <and other handling>

Not applicable.

7. MARKETING AUTHORISATION HOLDER

Sterling lab
57, SIPCOT Industrial Complex
Hosur-635 126 (T.N.) India.

8. MARKETING AUTHORISATION NUMBER(S)

H2022/CTD7382/13206

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

4th November 2021

10. DATE OF REVISION OF THE TEXT

18th August 2026