NAME OF THE MEDICINAL PRODUCT

ZOFU (Ketoconazole 2% w/w Dusting Powder)

1. QUALITATIVE AND QUANTITATIVE COMPOSITION

The active ingredient is Ketoconazole IP .... 2 % w/w

2. PHARMACEUTICAL FORM

Pharmaceutical form: Powder for topical application

Description: White coloured fine powder Filled with 75 gm HDPE container.

3. CLINICAL PARTICULARS

3.1 Therapeutic indications

Ketoconazole Dusting Powder 2% is used as a topical treatment for fungal infections of the skin due to the Tinea fungus, which is a dermatophyte fungus also known as ringworm. Tinea causes fungal infection in different parts of the body including ringworm of the foot, also known as Athlete's foot (tinea pedis), of the body (tinea corporis), of the groin (tinea cruris or jock itch), and of the scalp (tinea capitis).

Ketoconazole Dusting Powder 2% is also used to treat infection by the yeast fungus Malassezia, which causes Pityriasis versicolor, characterised by flaky discoloured patches that appear on the chest and back.

Ketoconazole Dusting Powder 2% is also effective against infection with the yeast fungus Candida, which causes cutaneous candidiasis, characterised by itchy red rash on various parts of the body, usually in warm, moist creased areas of skin, like under the arms and in the groin.

Ketoconazole Dusting Powder 2% is particularly useful for use on broken skin and if a drying effect is required. It can also be used for dusting inside socks, shoes or clothing where there is direct contact with an infected area of skin.

3.2 Posology and method of administration

Ketoconazole Dusting Powder 2% should be applied twice daily by sprinkling onto the affected area and surrounding skin, including broken skin.

It can also be used to dust the inside of socks, shoes or clothing that is in directed contact with infected skin.
One should continue to use your Ketoconazole Dusting Powder 2% until all symptoms of the infection have disappeared, which may be for 2-6 weeks and for a further 10 days after, to prevent relapse.
Wash your hands after using Ketoconazole Dusting Powder 2% to prevent spreading the infection and do not get the powder into your eyes. Also, avoid inhalation of the powder to prevent irritation of the airways.
Contraindications

- Allergic to ketoconazole or any ingredients in Ketoconazole Dusting Powder
- Pregnant or are breastfeeding, without discussion with your doctor

3.3 Special warnings and precautions for use

None.

3.4 Interaction with other medicinal products and other forms of interaction

The systemic absorption of topically applied ketoconazole is minimal and systemic interaction with other medicinal products is unlikely.

3.5 Fertility, pregnancy and lactation

There are no adequate and well-controlled studies in pregnant or lactating women.

3.6 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

The most commonly reported side effects when taking Ketoconazole Dusting Powder 2% include, burning sensation or irritation at the site of application, such as redness,
pain and swelling.

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 reaction to the National Regulatory Authority

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

Ketoconazole Dusting Powder 2% contains ketoconazole, a synthetic broad-spectrum antifungal that is used to treat a variety of fungal infections of the skin. Ketoconazole in Ketoconazole Dusting Powder 2% prevents growth of dermatophyte and yeast fungi by inhibiting the synthesis of ergosterol, an important component of fungal cell membrane that is not found in animal cells. This results in altering the permeability of the fungal cell membrane causing it to become weakened, so that the cell contents leak out, which kills the fungus, preventing the infection from spreading and relieving symptoms caused by the fungal infection, including pain and inflammation. When used as a topical antifungal, no detectable ketoconazole enters the blood, reducing risk of systemic side effects.

5.2 Pharmacokinetic properties

Ketoconazole is not absorbed systemically after topical administration, and minimally absorbed from the vagina. Ketoconazole does not cross the intact blood-brain barrier, and crosses to only a limited extent in fungal meningitis. Urinary concentrations of ketoconazole are usually low, but vaginal and vaginal tissue concentrations correlate with those in serum. Ketoconazole is 83.7% plasma protein (mainly albumin) bound, and 15.3% is erythrocyte bound, resulting in only 1% of free drug.

5.3 Preclinical safety data

There are no preclinical data available.

6.0 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Talc (Extra White) IP 927.6 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.

Special precautions for storage

Store below 30^0 C. Protect from light and moisture. Replace the cap immediately after use.

6.4 Nature and contents of container

Filled with 75 gm in HDPE container.

6.5 Special precautions for disposal <and other handling>

Not applicable.

7. MARKETING AUTHORISATION HOLDER

Manufacturer: STERLING LAB
57, SIPCOT INDUSTRIAL COMPLEX HOSUR-635126 TAMILNADU, INDIA
MAH holder: STERLING LAB
57,Sipcot Industrial complex

8. MARKETING AUTHORISATION NUMBER(S)

768

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

2022 July 04

10. DATE OF REVISION OF THE TEXT

2027 July 04