SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

FUNGOAL CREAM 1 % w/w

2. Qualitative and quantitative composition

Clotrimazole BP ..... 1.00 % w/w

Cream Base..... Q.S.

3. Pharmaceutical form

Topical Cream

A white to off white soft cream

4. Clinical particulars

4.1 Therapeutic indications

Fungoal cream is indicated for the topical treatment of candidiasis due to Candida albicans and Tinea versicolor due to Malassezia furfur . Fungoal cream is also indicated for the topical treatment of the following dermal infections : Tinea pedis, Tinea cruris and Tinea corporis due to Trichophyton rubrum, Trichophyton mentagrophytes, Epidermophyton floccosum and Microsporum canis.

4.2 Posology and method of administration

Gently massage sufficient Fungoal cream into the affected and surrounding skin areas twice a day in the morning and evening. Clinical improvement with relief of pruritus usually occurs within the first week of treatment with Fungoal cream. If the patient shows no clinical improvement after 4 weeks of treatment with Fungoal cream the diagnosis should be reviewed. **Method of Administration**

For topical application.

4.3 Contraindications

Fungoal cream is not suitable to those who have shown hypersensitivity to clotrimazole.

4.4 Special warnings and precautions for use

This product contains cetostearyl alcohol, which may cause local skin reactions (e.g. contact dermatitis).

4.5 Interaction with other medicinal products and other forms of interaction

Laboratory tests have suggested that, when used together, this product may cause damage to latex contraceptives. Consequently the effectiveness of such contraceptives may be reduced. Patients should be advised to use alternative precautions for at least five days after using this product.

4.6 Fertility, pregnancy and lactation

Fertility: No human studies of the effects of clotrimazole on fertility have been performed; however, animal studies have not demonstrated any effects of the drug on fertility.
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, but only under the supervision of a physician or midwife.
Lactation: Available Pharmacodynamic / toxicological data in animals have shown excretion of clotrimazole/metabolites in milk after intravenous administration. A risk to the suckling child cannot be excluded. A decision must be made whether to discontinue breast- feeding or to discontinue/abstain from clotrimazole therapy considering the benefit of breast-feeding for the child and the benefit of therapy for the woman.

4.7 Effects on ability to drive and use machines

Clotrimazole cream has no or negligible influence on the ability to drive or use machines.

4.8 Undesirable effects

As the listed undesirable effects are based on spontaneous reports, assigning an accurate frequency of occurrence for each is not possible. Immune system disorders: allergic reaction (syncope, hypotension, dyspnea, urticaria). Skin and subcutaneous tissue disorders: blisters, discomfort/pain, oedema, erythema irritation, peeling/exfoliation, pruritus, rash, stinging/burning.

Reporting of suspected adverse reactions:
Reporting suspected adverse reactions after authorisation of the medicinal product is important as it allows continued monitoring of the benefit–risk balance of the medicinal product. Healthcare professionals are requested to report any suspected adverse reactions to the marketing authorisation holder or, where applicable, via the national reporting system.

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 favorable to absorption) or inadvertent oral ingestion. There is no specific antidote.

However, in the event of accidental oral ingestion, gastric lavage is rarely required and should be considered only if a life-threatening amount of Clotrimazole has been ingested within the preceding hour or 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

ATC Code: D01A C01

Pharmacotherapeutic group: Antifungal for topical use – imidazole and triazole derivatives. Clotrimazole acts against fungi by inhibiting ergosterol synthesis. Inhibition of ergostero synthesis leads to structural and functional impairment of the fungal cytoplasmic membrane.
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. The mode of action of clotrimazole is primarily 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.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.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 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 mcg/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. In rats clotrimazole and/or its metabolites were secreted into milk at levels higher than in plasma by a

factor of 10 to 20 at 4 hrs after administration, followed by a decline to a factor of 0.4 by 24 hrs.

6. Pharmaceutical particulars

6.1 List of excipients

Cetomacrogol 1000

Cetostearyl alcohol

White Soft Paraffin

Sodium Acid Phosphate

Chlorocresol

Light Liquid Paraffin

Propylene Glycol

Purified water

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store at temperature not exceeding 30°C; do not freeze.

6.5 Nature and contents of container

A Lami tube, with a membrane seal at the nozzle, internal epoxy lacquer, latex end seal band in the crimp seal and a white plastic cap for reclosure after piercing membrane.

Pack sizes: The cream is filled into lami tubes with white colour stand-up caps and enclosed in an outer carton. Pack sizes available are 20g.

6.6 Special precautions for disposal and other handling

Not applicable.

7. Marketing authorisation holder

Kremoint Pharma Pvt. Ltd., B-8 Additional MIDC, Ambernath Ambernath (E). Thane 421506.

Manufacturer
Kremoint Pharma Pvt. Ltd., B-8 Additional MIDC, Ambernath Ambernath (E). Thane 421506.

8. Marketing authorization number(s):

H2022/CTD8325/17035

9. Date of first authorisation/renewal of the authorisation

13/12/2023

10. Date of revision of the text

13/12/2023