Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:

Eberfine Cream 1% w/w

2. Qualitative and quantitative composition

Eberconazole Nitrate
Eq. to Eberconazole..... 1.0% w/w
Preservatives:
Methylparaben USP..... 0.1% w/w
Propylparaben USP..... 0.025% w/w
Cream Base..... q.s.

Excipients with known effect :
Cetostearyl Alcohol
Propylene Glycol
Methyl Paraben,
Propyl Paraben,
For a full list of excipients, see section 6.1.

3. Pharmaceutical form

Semi – Solid Dosage Form (Cream)

4. Clinical particulars

4.1 Therapeutic indications

Eberconazole cream 1% is a broad-spectrum antifungal agent used in the treatment of superficial fungal skin infections caused by dermatophytes and yeast infections of the skin

4.2 Posology and method of administration

Posology

Adults it should be applied twice a day for four weeks. If after this period of treatment no clinical improvement is observed, the diagnosis should be reconsidered.
Appropriate hygienic measures must be maintained to prevent possible reinfection.

Elderly patients

It is not necessary to modify the dosage regimen recommended in adults.
Renal and / or hepatic insufficiency it is not necessary to modify the

recommended dosage regimen in adults with normal renal and / or hepatic function.
Pediatric population No specific studies are available in this population group.

Method of administration

Topical
The cream should be applied with the tips of the fingers, preventing the tube from coming into direct contact with the infected area. The cream will spread homogeneously, in sufficient quantity to cover the extension of the lesion and adjacent areas, and its penetration will be favored through a light massage. In intertriginous lesions, a small amount of the cream will be applied to prevent maceration of the skin. It is important to close the tube well after each application.

4.3 Contraindications

- It is contraindicated in patients with hypersensitivity to other imidazole antifungals, or hypersensitivity to the active substance or to any of the excipients such as methylparaben and propylparaben
- Use on eyes, mucous membranes, or open, damaged, or broken skin is contraindicated.
- It should not be used if there is a history of allergic reactions to azole antifungals

4.4 Special warnings and precautions for use

It should not be used ophthalmic or applied to mucous membranes. In case of contact with the eyes, it is advisable to wash them with plenty of water. Occlusive bandages should not be used or they should not perspire, since the development of yeasts and the consequent skin irritation could be favored.
If a dermal reaction suggests sensitization or irritation due to the use of this medication, the treatment should be interrupted and appropriate corrective measures should be instituted.
There are no specific clinical studies available on the use of this medicine in children.
This medicine may cause local reactions on the skin (such as contact dermatitis) because it contains Cetostearyl alcohol.
Hypersensitivity reactions: This product contains methylparaben and propylparaben, which may cause allergic reactions, including delayed hypersensitivity in sensitive individuals.Patients with known hypersensitivity to eberconazole, other imidazole antifungals, parabens, or any excipients should avoid use

4.5 Interaction with other medicinal products and other forms of interaction

Although specific interactions with other medications have not been described, it is recommended not to use concomitantly with other preparations of cutaneous use in order to avoid the risk of potential interactions between treatments.

4.6 Pregnancy and Lactation

No adequate data are available from the use of eberconazole in pregnant women. Animal studies are insufficient with respect to effects on pregnancy, embryonic and fetal development, parturition and postnatal development. Caution should be exercised when prescribing it to pregnant women.
It is not known if eberconazole is excreted in breast milk, so caution should be exercised when prescribing it to women who are breastfeeding

4.7 Effects on ability to drive and use machines

It has not been observed that this medication affects the ability to drive and use machines.

4.8 Undesirable effects

In clinical studies performed with this drug, approximately 3% of patients experienced some adverse reaction Common and uncommon adverse reactions.

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

There have been no reports of Over dosage through the skin. However, in case of accidental ingestion and systemic exposure to Eberconazole, appropriate symptomatic therapy will be applied.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacodynamic properties Pharmacotherapeutic group (ATC code): Antifungals for topical use (D01AC)
Mechanism of action
Eberconazole is an azole antifungal agent, which inhibits the synthesis

of ergosterol, an essential component of the cytoplasmic membrane. This leads to an alteration in its structure and function, thereby inhibiting the growth of the fungus.

Pharmacodynamic effects

Eberconazole is an imidazole derivative with antifungal antigen for the cutaneous treatment of dermatophytosis. In vitro studies suggest that eberconazole nitrate, like the rest of imidazoles, inhibits the synthesis of ergosterol, a fundamental component of the cytoplasmic membrane, causing an alteration of the structure and function of the same that determines the growth inhibition of the fungus.

Eberconazole has a spectrum of antifungal activity that includes dermatophytes, yeasts and other pathogenic fungi. Eberconazole has an MIC90 less than 1µg/ ml against the most common pathogenic dermatophytes belonging to the genera Trichophyton and Microsporum as well as against Epidermophyton floccosum. It has also shown activity against yeasts of the genus Candida from clinical isolates, highlighting its activity on C. glabrata (MIC90 0.1 µg / ml) and C. kruseii (MIC90 0.125 µg / ml).

5.2 Pharmacokinetic properties

In an open and uncontrolled clinical trial, Eberconazole Nitrate Cream was administered twice a day for 28 days to 12 healthy volunteers. No detectable levels of eberconazole in plasma or in plasma were observed to determine systemic absorption at 28 days of treatment urine (detection limits of 1.1 ng / ml and 1.0 ng / ml, respectively) at the end of the study period.

5.3 Preclinical safety data

Not Applicable

6. Pharmaceutical Particulars

6.1 List of Excipients

Methyl Paraben, Propyl Paraben, Macrogol Cetostearyl ether, Cetostearyl Alcohol, Glyceryl Monostearate, Light Liquid Paraffin, Dimethicone, Propylene Glycol, White Soft Paraffin Sodium Hydroxide, Purified Water.

6.2 Incompatibilities:

Not Applicable

6.3 Shelf life:

2 years

6.4 Special precautions for storage:
Store at a temperature not exceeding 30°C. Do not freeze.

6.5 Nature and contents of container:
30gm, Lami tubes internally coated with an epoxy resin based lacquer and closed with a polypropylene cap.

6.6 Special precautions for disposal and other handling:
No special requirements.

7. Marketing Authorization Holder
KLM Laboratories Pvt Ltd.
1004, Hubtown Viva, Western Express Highway, Jogeshwari (E), Mumbai-400060, India.

8. Marketing Authorization Number
CTD8357

9. Date of first authorization/renewal of the authorization
23/02/2024

10. Date of revision of the text
10/05/2025