

Summary of Product Characteristics for Pharmaceutical Products

1.Name Of The Medicinal Product

EBERNET

EBERCONAZOLE CREAM 1% W/W

2.Qualitative And Quantitative Composition

Eberconazole Nitrate

Eqv. To Eberconazole 1% w/w

Cream Base Q.S.

3.Pharmaceutical Form

Semi Solid topical dosage form, Cream

A white color, homogenous soft mass filled in printed lami tube.

4.Clinical Particulars

4.1 Therapeutic indications

This medication helps in treating the following problems in the human body:

- Allergic Disorders
- Skin Infection - used in the treatment of superficial skin infections caused by dermatophytes such as Tinea corporis, Tinea pedis, etc.

4.2 Posology and method of administration

For topical use only, EBERNET Cream, 1% is not for ophthalmic, oral, or intravaginal use. When treating infection, a thin layer of EBERNET Cream, 1% should be applied to the affected area and approximately 1 inch of the immediate surrounding area(s) once daily for two (2) weeks. EBERNET Cream, 1% should be applied to the affected area and approximately 1 inch of the immediate surrounding area(s) once daily for one (1) week. Apply the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose. Do not apply a double dose to make up for the missed one.

4.3 Contraindications

Hypersensitivity

4.4 Special warnings and precautions for use

This medicine is not recommended for use in patients with a known allergy to eberconazole or any other inactive ingredients present along with it.

4.5 Interaction with other medicinal products and other forms of interaction

This medicine is not recommended for use in patients with a known allergy to eberconazole or any other inactive ingredients present along with it.

4.6 Pregnancy and Lactation

4.7 Effects on ability to drive and use machines

4.8 Undesirable Effects

A patient can suffer from the following side effects:

- Skin Thinning
- Contact Dermatitis
- Itching
- Erythema
- Burning sensation at the application site
- Rash

4.9 Overdosage

None

5. Pharmacological Properties

5.1 Pharmacodynamic Properties

Mechanism of Action

Eberconazole exerts fungicidal or fungistatic activity depending on concentration, being fungicidal at higher concentration and fungistatic at lower concentrations.

Eberconazole prevents fungal growth by inhibiting ergosterol synthesis, an essential component of the fungal cytoplasmic membrane leading to structural and functional changes. It prevents the fungal ergosterol synthesis by inhibiting lanosterol 14 α -

demethylase enzyme that is responsible for the formation of 14 α -methylsterols (precursor of ergosterols). Studies have shown that eberconazole binds to the phospholipid fraction of the cell and affects sterol synthesis intracellularly. At high concentrations, it causes the leakage of small molecules such as potassium ions, amino acids, inorganic phosphate and nucleotides from the fungal cell leading to cell death.

The anti-inflammatory activity comparable to acetyl salicylic acid and ketoprofen, shown in vivo by eberconazole is attributable to the inhibition of 5-lipoxygenase and to a lesser extent of cyclooxygenase-2.

Pharmacodynamics properties

None

5.2 Pharmacokinetic properties

None

5.3 Preclinical safety data

None

6. Pharmaceutical particulars

6.1 List of excipients

Glycerol Monostearate BP
Cetomacrogol Emulsifying Wax
BP
Cetostearyl Alcohol BP
Light Liquid Paraffin BP
Propylene Glycol BP
Disodium Edetate BP
Sodium Methyl
Hydroxybenzoate BP
Sodium Propyl
Hydroxybenzoate BP
Benzyl Alcohol BP
Purified Water BP

6.2 Incompatibilities

None

6.3 Shelf life

2 year

6.4 Special precautions for storage

Do not store above 30°C. Protect from light.

6.5 Nature and contents of container

A white color, homogenous soft mass filled in 15 gm printed lami tube. Such one tube is packed in printed carton with packing insert.

6.6 Special precautions for disposal and other handling

No Special Requirements.

7. Marketing Authorisation Holder

SALUD CARE (I) PRIVATE LIMITED

435, Kishanpur Jamalpur,

Opp. Pharma College of Roorkee, Roorkee- 247 661

Haridwar, Uttarakhand, INDIA

8. Marketing Authorisation Number

H2022/CTD6347/17852

9. Date of revision of the text

2022 November 08

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