For the use only of Registered Medical Practitioners or a Hospital or a Laboratory

ZODERM E CREAM

1. GENERIC NAME

Oxiconazole Nitrate Cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Contains:
Oxiconazole Nitrate USP equivalent to
Oxiconazole 1% w/w
Benzoic Acid I.P. 0.2% w/w
(as preservative)

List of Excipients

Benzoic acid (as preservative), Cetyl alcohol, Stearyl alcohol, White soft paraffin, Propylene glycol, Polysorbate 60 and Purified water.

3. DOSAGE FORM AND STRENGTH

Cream.

For information on strength refer section *2. Qualitative and Quantitative Composition* above.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indication

ZODERM E CREAM is indicated for the topical treatment of superficial fungal infections of the skin.

4.2 Posology and Method of Administration

1 application per day after washing with a non-acidic soap and drying the skin. The duration of treatment depends on the infecting organisms and the places of infection: usually 3 weeks for dermatophytosis, 2 weeks for tinea versicolor and candidiasis.

4.3 Contraindications

Hypersensitivity to imidazole derivatives, or to any of the excipients listed in *section 2. Qualitative and Quantitative Composition*.

4.4 Special Warnings and Precautions for Use

Precautions for use

Avoid the use of soaps with an acidic pH which favors the multiplication of candida;

Avoid applying near the eyes.

ZODERM E CREAM contains 2 mg of benzoic acid per gram of cream. Benzoic acid may cause local irritation. Benzoic acid may increase the risk of jaundice (yellowing of the skin and eyes) in newborns (up to 4 weeks).

ZODERM E CREAM contains cetyl alcohol and stearyl alcohol and may cause local skin reactions (for example: contact dermatitis).

4.5 Drug Interactions

Not known.

4.6 Use in Special Population

Pregnancy

Although no teratogenic effects have been observed in animal studies, it is recommended *ZODERM E CREAM* should not be administered during the first trimester of pregnancy.

Lactation

Oxiconazole is excreted in breast milk and should be used with caution during breast-feeding. However, because topically applied oxiconazole is poorly absorbed, the exposure risk of a breast-feeding infant is low. Instruct mothers not to apply *ZODERM E CREAM* topically to the breast while breast-feeding. Consider the benefits of breast-feeding, the risk of potential infant drug exposure, and the risk of an untreated or inadequately treated condition.

4.7 Effects on Ability to Drive and Use Machines

The effects on the ability to drive and use machines have not been studied. No effect on the ability to drive and use machines is expected.

4.8 Undesirable Effects

Some signs of local irritation (pruritus, burning, erythema) have been reported; they lead spontaneously to treatment discontinuation.

The appearance of systemic effects is unlikely given the low rate of absorption on intact skin level, which should be handled with care on a large area or damaged skin, particularly on infants (due to the surface / weight ratio and the effect of occlusion of layers).

4.9 Overdose

There are no clinical data on the effects of overdose.

5. PHARMACOLOGICAL PROPERTIES

5.1 Mechanism of Action

Oxiconazole is an imidazole antifungal derivative whose antifungal activity occurs secondary to inhibition of ergosterol biosynthesis. Ergosterol is a critical component of cellular membrane integrity. Oxiconazole inhibits 14-alpha-demethylase, which impairs the biosynthesis of ergosterol, which is important for the fungal cytoplasmic membrane. Oxiconazole and other azole antifungal agents may directly increase fungal cytoplasmic membrane permeability through the high concentrations that are achieved with topical application.

5.2 Pharmacodynamic Properties

Pharmacotherapeutic group: Antifungal of the imidazole class;
ATC Code: D01AC11

Fungicide: *Trichophyton mentagrophytes, Candida albicans*.

Antibacterial: *Staphylococcus aureus, Streptococcus fecalis*.

5.3 Pharmacokinetic Properties

Low transepidermal penetration (<1 %).

Undetectable plasma concentration.

Transcutaneous passage may be increased in case of damaged skin.

6. NONCLINICAL PROPERTIES

Non-clinical data based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenicity, and reproductive functions, revealed no special hazard for humans.

7. DESCRIPTION

Cream

Contains:
Oxiconazole Nitrate USP equivalent to
Oxiconazole 1% w/w
Benzoic Acid I.P. 0.2% w/w
(as preservative)

List of Excipients

Benzoic acid (as preservative), Cetyl alcohol, Stearyl alcohol, White soft paraffin, Propylene glycol, Polysorbate 60 and Purified water.

8. PHARMACEUTICAL PARTICULARS

8.1 Incompatibilities

No incompatibilities have been identified.

8.2 Shelf Life

The expiry date is indicated on the label and packaging.

8.3 Packaging Information

Tube in a carton.

8.4 Storage and Handling Instructions

Store at temperature below 25° C. Do not freeze.

Keep out of reach of children.

For external use only.

Do not accept if Tagger on tube nozzle is broken.

9. PATIENT COUNSELLING INFORMATION

Registered Medical Practitioners may counsel their patients (and/or their patients' caregiver as applicable) about the special warnings and precautions for use, drug interactions, undesirable effects, and any relevant contra-indications of *ZODERM E CREAM*. Patients (and/or patients' caregiver) may also be informed about posology, method of administration and storage/handling information as applicable.

10. DETAILS OF MANUFACTURER

The Manufacturing Site details are mentioned on the label and packaging.

For further information please contact:
GlaxoSmithKline Pharmaceuticals Limited.
Registered Office
Dr. Annie Besant Road, Worli
Mumbai - 400 030.

11. DETAILS OF PERMISSION OR LICENCE NUMBER WITH DATE

Manufacturing License number is indicated on the label and packaging.

12. DATE OF REVISION

14-JUN-2024

Trade marks are owned by or licensed to the GSK group of companies.

ZODE/PI/IN/2024/01

Adapted from

- *Fonx (oxiconazole 1 % cream) SmPC dated 30 March 2021. Available from: http://agence-prd.ansm.sante.fr/php/ecodex/frames.php?specid=60797376&typedoc=R&ref=R0370241.htm*
- *Clinical Pharmacology (Oxiconazole Nitrate 1% Topical Cream) available from: https://www.clinicalkey.com/pharmacology/monograph/1487*