1. Name of medicinal product

SKINFIX PLUS CREAM (Ketoconazole, Clobetasol Propionate & Neomycin Sulphate Cream)

2. Composition:

Each Gram contains:
Ketoconazole BP ..... 2.00% w/w
Clobetasol Propionate USP .....0.05% w/w
Neomycin Sulphate USP.....5000 I.U.
Cream base ..... q.s.

For the full list of excipients see, section 6.1

3. Pharmaceutical Form:

Topical

4. Clinical Particulars

4.1 Indication

For topical application in the treatment of dermatophyte infections of the skin such as tineacorporis,tineacruris,tineamanusandtineapedisinfectionsduetoTrichophytonspp,Microsporonspp and Epidermophyton spp. SKINFIX PLUS is also indicated for the treatment of cutaneous candidosis (including vulvitis), Tinea (pityriasis) versicolor and Seborrhoeic dermatitis caused by Malassezia (previously called Pityrosporum) spp.

Clobetasol is a very potent topical corticosteroid indicated for adults, elderly and children over 1 year for the short term treatment only of more resistant inflammatory and pruritic manifestations of steroid responsive dermatoses unresponsive to less potent corticosteroids. These include the following:

- Psoriasis(excluding wides pread plaquepsoriasis)
- Recalcitrant dermatoses
- Lichen planus
- Discoid lupus erythematosus
- Other skin conditions which do not respond satisfactorily to less potent steroids.

Neomycin Sulphate is an antibiotic used to reduce the risk of infection during surgery of the bowel. Neomycin is also used to reduce the symptoms of hepatic coma.

4.2 Posology and Administration

Ketoconazole cream is for use in adults.
Cutaneous candidosis, Tinea corporis, Tinea cruris, Tinea manus, Tinea pedis and Tinea(pityriasis) versicolor:
It is recommended that SKINFIX PLUS be applied once or twice daily to cover the affected and immediate surrounding area.

The usual duration of treatment is: Tinea versicolor 2–3 weeks, yeast infections 2-3 weeks,

Tinea cruris 2-4 weeks, Tinea corporis 3–4 weeks, Tinea pedis 4-6 weeks.
Seborrheic dermatitis:
SKINFIX PLUS should be applied to the affected areas once or twice daily.
The usual initial duration of treatment in seborrheic dermatitis is 2 to 4 weeks. Maintenance therapy can be applied intermittently (once weekly)in seborrheic dermatitis.
Treatment should be continued until a few days after the disappearance of all symptoms. Thediagnosisshouldbereconsideredifnoclinicalimprovementisnotedafter4weeksoftreatment.
General measures in regard to hygiene should be observed to control sources of infection or reinfection.
Seborrhoeic dermatitis is a chronic condition and relapse is highly likely
.Method of administration: Cutaneous administration.

4.3 Contraindication

It is contra-indicated in patients with a known hypersensitivity to any of the ingredients or to ketoconazole itself.

4.4 Special Warning & precautions for use

Cream is not for ophthalmic use.

If Co-administered with a topical corticosteroid, to prevent a rebound effect after stopping a prolonged treatment with topical corticosteroids it is recommended to continue applying amildtopicalcorticosteroidinthemorningandtoapplycreamintheevening, and to subsequently and gradually withdraw the topical corticosteroid therapy over a period of 2-3weeks.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, Pregnancy and lactation

There are no adequate and well-controlled studies in pregnant or lactating women. Data on alimitednumberofexposedpregnanciesindicatenoadverseeffectsoftopicalketoconazoleonpregnancy or on the health of the foetus/newborn child. Animal studies have shown reproductive toxicity at doses that are not relevant to the topical administration of Ketoconazole.

Plasma concentrations of ketoconazole are not detectable after topical application of SKINFIX PLUS to the skin of non-pregnant humans. (See Pharmacokinetic properties, section 5.2)There are no known risks associated with the use of SKINFIX PLUS in pregnancy or lactation.

4.7 Effects on ability to drive and use machines

Not available

4.8 Undesirable effects

The most commonly adverse reactions were application site pruritus, skin burning sensation, and application site erythema.

4.9 Overdose

Topical Application

Excessive topical application may lead to erythema, oedema and a burning sensation, which will is appear upon discontinuation of the Treatments

Ingestion

In the event of accidental ingestion, supportive and symptomatic measures should be carried out.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmaco therapeutic group: Antifungals for Topical Use, Imidazole and triazole derivatives

ATC Code: D01AC08
Usually ketoconazole cream acts rapidly on pruritus, which is commonly seen indermatophyte and yeast infections, as well as skin conditions associated with the presence of Malassezia spp. This symptomatic improvement is observed before the first signs of healing are observed.
Ketoconazole, a synthetic imidazole dioxolane derivative, has a potent antimycotic activity against dermatophytes such as Trichophyton spp., Epidermophyton floccosum and Microsporum spp. and against yeasts, including Malassezia spp. and Candida spp. The effecton Malassezia spp. is particularly pronounced.

5.2 Pharmacokinetic properties

Plasma concentrations of ketoconazole were not detectable after topical administration of SKINFIX PLUS in adults on the skin. In one study in infants with seborrhoeic dermatitis (n =19), where approximately 40 g of SKINFIX PLUS was applied daily on 40% of the body surface area, plasma levels of ketoconazole were detected in 5 infants, ranging from 32 to133ng/mL.

6. Shelf Life

36 months

6.1 Special precaution for Storage

Do not store above 30°C.

6.2 Nature and contents of container

30g tube pack in a carton along with insert.

7 Marketing Holder

Marketed By:

EVERDESTINY PHARMACEUTICALS LTD

Lagos, Nigeria.

Manufacturer

OHAD PHARMACEUTICALS PVT.LTD.

Plot no.222&223, GIDC, Industrial Estate, Palej–

392220, District: Bharuch, Gujarat, India.