JOMIASKIN PLUS

Ketoconazole, Clobetasol Propionate & Neomycin Sulphate Cream

1.3.ISUMMARYOFPRODUCTCHARACTERISTICS (SMPC)

1. Name of medicinal product

Ketoconazole,Clobetasol Propionate &Neomycin Sulphate Cream

2. Composition:

Ketoconazole BP 2 00%w/w

Clobetasol Propionate BP .....0.05% w/w

Neomycin Sulphate USP.....5000 I.U.

Cream base..... q.s.

3. Pharmaceutical Form:

Topical

3.1 BATCH FORMULA:-

PRODUCT NAME: SKINFIX PLUS (KETOCONAZOLE, CLOBETASOL PROPIONATE & NEOMYCIN SULPHATE CREAM)

COMPOSITION:

Ketoconazole BP 2 00% w/w

Clobetasol Propionate BP.....0.05% w/w

Neomycin Sulphate USP.....5000 I.U.

Cream base .....q.s.

FORMULA

INGREDIENTS	Quantity	Overages(%)	Std. Qty Per Batch	REFERENCE
	ACTIVE	INGREDIENT		
* Neomycin Sulphate	5000 IU		3.350	USP
*Ketoconazole	2.00% w/w		10.000	BP
*Clobetasol Propionate	0.05% w/w		0.250	BP
	INACTIVE INGREDIENTS			
Light Liquid Paraffin	-	-	30.000	BP
White Soft Paraffin	-	-	62.000	BP
Cetomacrogol-1000	-	-	13.500	BP
CetoSteryl Alcohol	-	-	50.000	BP
Propylene Glycol	-	-	40.000	BP
Methyl Paraben	-	-	1.000	BP
Propyl Paraben	-	-	0.100	BP
Purified Water	-	-	QS to 500 Kg	BP

4. ClinicalParticulars

4.1 Indication

For topical application in the treatment of dermatophyte infections of the skin such as tinea corporis, tinea cruris, tinea manus and tinea pedis infections due to Trichophyton spp, Microsporon spp and Epidermophyton spp. JOMIASKIN 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 widespread plaque psoriasis)

– Recalcitrant dermatoses

– Lichen planus

– Discoid lupus erythematosus

– Other skin conditions which do not respond satisfactorily to less potent steroids.

Neomycin Sulfate is an antibiotic used to reduce the risk of infection during surgery of the bowel. Neomycin is also used to reduce the symptoms of hepaticcoma.

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 JOMIASKIN be applied once or twice daily to cover the affected and immediate surrounding area. The usual duration of treatment is:tinea versicolor2-3 weeks, yeast infections 2-3 weeks,tinea cruris 2- 4weeks, tinea corporis 3-4 weeks, tinea pedis 4-6weeks.

Seborrheic dermatitis:

JOMIASKIN 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. The diagnosis should be reconsidered if no clinical improvement is noted after 4weeks of treatment. 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 a mild topical corticosteroid in the morning and to apply cream in the evening, 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 a limited number of exposed pregnancies indicate no adverse effects of topical ketoconazole on pregnancy 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 JOMIASKIN to the skin of non-pregnant humans. (See Pharmacokinetic properties, section 5.2)There are no known risks associated with the use of JOMIASKIN 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 disappear 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
Pharmacotherapeutic group: Antifungals for Topical Use, Imidazole and triazole derivatives

ATC Code: DO1AC08

Usually ketoconazole cream acts rapidly on pruritus, which is commonly seen in dermatophyte 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 activityagainst dermatophytes such as Trichophyton spp., Epidermophytonfloccosum and Microsporum spp. and against yeasts, including Malassezia spp. and Candida spp. The effect on Malassezia spp. is particularly pronounced.

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

5.3 Preclinical safety data
Preclinical data reveal no special hazard for humans based on conventional studies including primary ocular or dermal irritation, dermal sensitisation and repeat-dose dermal toxicity.

Ketoconazole has been shown to be teratogenic (syndactylia and oligodactylia) in the rat when given orally in the diet at 80 mg/kg/day;

6. Shelf Life
36months

6.2 Incompatibilities
Not applicable.

7. Special precaution for Storage

Do not store above 25°C.

8. Nature and contents of container

30g tube pack in a carton along with insert.

9. Marketing Holder

Jomia pharmaceuticals LTD

10. Manufacturer

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