

FLOURISH PHARMA	
BRAND NAME:	JOMIADERM CREAM
GENERIC NAME:	Ketoconazole, Betamethasone Dipropionate and Gentamycin Sulphate Cream

SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)

1. Name of medicinal product

JOMIADERM CREAM (Ketoconazole, Betamethasone Dipropionate and Gentamycin Sulphate Cream)

2. Qualitative and Quantitative Composition:

Each gram contains:

Ketoconazole BP2.00% w/w

Betamethasone Dipropionate USP

Equivalent to Betamethasone0.05% w/w

Gentamycin Sulphate BP

Equivalent to Gentamycin0.10% w/w

Cream Baseq.s.

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INGREDIENTS	Quantity	Overages (%)	Std. Qty per batch 450Kg	REFERENCE
ACTIVE INGREDIENT				
Ketoconazole	2.00% w/w	---	9.0	BP
Betamethasone Dipropionate Equivalent to Betamethasone	0.05% w/w	---	0.37	USP
Gentamycin Sulphate BP Equivalent to Gentamycin	0.10%w/w	--	0.91	BP
INACTIVE INGREDIENTS				
Ceto Steryl Alcohol	--	---	36.0	BP
Light Liquid Paraffin	--	---	57.69	BP
Hard Paraffin wax	--	---	18.90	BP
Micro crystalline wax	--	---	4.50	BP
Propylene Glycol	--	---	18.00	BP
Butyl hydroxy toluene	--	---	0.225	BP
Methyl Paraben	--	---	0.72	BP
Propyl Paraben	--	---	0.18	BP
Di sodium EDTA	--	---	0.45	BP
Disodium hydroxy orthophosphate anhydrous	--	---	0.0675	BP
Disodium hydroxy orthophosphate anhydrous	--	---	0.315	BP
Perfume Lavender	--	---	0.225	BP
Purified Water	--	---	QS to 500 Kg	BP

3. Pharmaceutical Form:

Topical

4. Clinical Particulars

4.1 Indication

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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. JOMIADERM is also indicated for the treatment of cutaneous candidosis (including vulvitis), tinea (pityriasis) versicolor and Seborrhoeic dermatitis caused by Malassezia (previously called Pityrosporum) spp.

Betamethasone 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.

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

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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 JOMIADERM 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:

JOMIADERM 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 4 weeks 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 2-3 weeks.

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.

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Plasma concentrations of ketoconazole are not detectable after topical application of JOMIADERM the skin of non-pregnant humans. (See Pharmacokinetic properties, section 5.2) There are no known risks associated with the use of JOMIADERM 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: D01AC08

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 activity against dermatophytes such as *Trichophyton* spp., *Epidermophyton floccosum* 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 JOMIADERM adults on the skin. In one study in infants with seborrhoeic dermatitis (n =19), where approximately 40 g of JOMIADERM was applied daily on 40% of the body surface area, plasma levels of ketoconazole were detected in 5 infants, ranging from 32 to 133 ng/mL.

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6.0 Pharmaceutical particulars

6.1 List of excipients

Ceto Steryl Alcohol
 Light Liquid Paraffin
 Hard Paraffin wax
 Micro crystalline wax
 Propylene Glycol
 Butyl hydroxy toluene
 Methyl Paraben
 Propyl Paraben
 Di sodium EDTA
 Disodium hydroxy orthophosphate anhydrous
 Perfume Lavender
 Purified Water

6.2 Incompatibilities

Not Applicable

6.3 Shelf Life

36 months

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6.4 Special precaution for Storage

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

6.5 Nature and contents of container

30 g tube pack in a carton along with insert.

7.0 Marketing Holder

JOMIA PHARMACEUTICALS
Covenant School Road , Amakifeke
Orlu, City:- IMO state ,Nigeria

Manufacturer

Flourish Pharma ,
24E,GOA-IDC,Daman
Ind.Estate,Daman (U.T.) India.

8.0 Marketing authorisation number(s)

9.0 Date of first authorisation/renewal of the authorisation

10.0 Date of revision of the text