1. Name of the Medicinal Product

(a) Product Name : FEXOCLEAR CREAM
(b) Pharmaceutical Dosage Form : Cream

2. Quality and Quantitative Composition

(a) Qualitative Declaration, the active substance should be declared by its recommended INN. Accompanied by its salt or hydrate form if relevant.

Composition:
Each gram contains:

Ketoconazole	B.P.	10 mg
Clobetasol propionate	U.S.P.	0.25 mg
Neomycin Sulphate	U.S.P.	
Eq. to Neomycin		5000 IU

(b) Quantitative Declaration, the quantity of the active substance must be expressed per dosage unit

Sr. No.	Name of the Materials	Specification	Label Claim	Quantity	Active/ Inactive
1	Ketoconazole	B.P.	10 mg	1.500 kg	Active
2	Clobetasol Propionate	U.S.P.	0.25 mg	37.5000 gm	Active
3	Neomycin Sulphate Eq. to Neomycin	U.S.P.	5000 IU	2.1856 kg	Active

3. Pharmaceutical Form Visual description of the appearance of the product (colour, markings, etc.) e.g.:

Off white colour cream having characteristic odour filled in printed lemi tube.

4. Clinical Particulars

4.1 Therapeutic Indications:

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

4.2 Posology and method of administration:

Posology

Apply to the affected area once a day, depending on the severity of the infection, the cream may be applied on the affected area twice daily when necessary. Generally, the duration of application depends on the type of infecting organism; Treat as bellows for die following:
Tinea Corporis 2 weeks; Tinea Cruris 2 weeks; Tinea Pedis 4 weeks; Tinea Manus 4 weeks.

Infection normally resistant to antifungal agents 4-6 weeks.

Method of administration
Topical administration only.

4.3 Contraindications:

Ketoconazole, Clobetasol Propionate & Neomycin Sulfate Cream is contra-indicated in patients with a known hypersensitivity to any of the ingredients or to ketoconazole itself.

4.4 Special warning and precautions for use:

Ketoconazole, Clobetasol Propionate & Neomycin Sulfate 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 Ketoconazole, Clobetasol Propionate & Neomycin Sulfate Cream in the evening, and to subsequently and gradually withdraw the topical corticosteroid therapy over a period of 2-3 weeks.

Ketoconazole, Clobetasol Propionate & Neomycin Sulfate Cream contains 6000 mg propylene glycol in each 30 g tube, which is equivalent to 200 mg/g.

Ketoconazole, Clobetasol Propionate & Neomycin Sulfate Cream contains cetyl alcohol and stearyl alcohol, which may cause local skin reactions (e.g. contact dermatitis).

4.5 Interaction with other medicinal products and other forms of interactions:
No interaction studies have been performed.

4.6 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 Ketoconazole Cream to the skin of non-pregnant humans. (See Pharmacokinetic properties, there are no known risks associated with the use of Ketoconazole, Clobetasol Propionate & Neomycin Sulfate Cream in pregnancy or lactation.

4.7 Effects on ability to drive and use machine:

Ketoconazole, Clobetasol Propionate & Neomycin Sulfate Cream has no influence on the ability to drive and use machines.

4.8 Undesirable effects:

The safety of Ketoconazole, Clobetasol Propionate & Neomycin Sulfate Cream was evaluated in 1079 subjects who participated in 30 clinical trials. Ketoconazole, Clobetasol Propionate & Neomycin Sulfate Cream was applied topically to the skin. Based on pooled safety data from these clinical trials, the most commonly reported (≥1% incidence) adverse reactions were (with % incidence): application site pruritus (2%), skin burning sensation (1.9%), and application site erythema (1%).

Including the above-mentioned adverse reactions, the following table displays adverse reactions that have been reported with the use of Ketoconazole, Clobetasol Propionate & Neomycin Sulfate Cream from either clinical trial or postmarketing experiences. The displayed frequency categories use the following convention:

Very common (≥1/10)

Common (≥1/100 to <1/10)

Uncommon (≥1/1,000 to <1/100)

Rare (≥1/10,000 to <1/1,000)

Very rare (<1/10,000)

Not Known (cannot be estimated from the available clinical trial data).

System Organ Class	Adverse Reactions		
	Frequency Category		
	Common (≥1/100 to <1/10)	Uncommon (≥1/1,000 to <1/100)	Not Known
Immune System Disorders		Hypersensitivity	

Skin and Subcutaneous Tissue Disorders	Skin burning sensation	Bullous eruption Dermatitis contact Rash Skin exfoliation Sticky skin	Urticaria
General Disorders and Administration Site Conditions	Application site erythema Application site pruritus	Application site bleeding Application site discomfort Application site dryness Application site inflammation Application site irritation Application site paresthesia Application site reaction	

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

4.9 Overdose:
Topical Application

Excessive topical application may lead to erythema, oedema and a burning sensation, which will disappear upon discontinuation of the treatment.

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

Usually Ketoconazole, Clobetasol Propionate & Neomycin Sulfate 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.

A study in 250 patients has shown that application twice daily for 7 days of ketoconazole 2% cream vs clotrimazole 1% cream for 4 weeks on both feet demonstrated efficacy in patients with tinea pedis (athlete's foot) presenting lesions between the toes. The primary efficacy endpoint was negative microscopic KOH examination at 4 weeks. Ketoconazole 2% treatment showed equivalent efficacy to 4 weeks clotrimazole 1% treatment. There was no evidence of relapse following treatment with ketoconazole cream at 8 weeks.

5.2 Pharmacokinetic Properties:

Plasma concentrations of ketoconazole were not detectable after topical administration of Ketoconazole Cream in adults on the skin. In one study in infants with seborrhoeic dermatitis (n = 19), where approximately 40 g of Ketoconazole, Clobetasol Propionate & Neomycin Sulfate Cream 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.

5.3 Preclinical Safety Data:
Effects in non-clinical studies were observed only at exposures considered sufficiently in excess of the maximum human exposure indicating little relevance to clinical use.

6 Pharmaceutical Particulars

6.1 List of excipients:

Excipients	Reference
Ceto-stearyl Alcohol	B.P
Cetomacragol-1000	B.P
Liquid paraffin Heavy	I.H
Chlorocresol	B.P
Methyl paraben sodium	B.P
Propyl paraben sodium	B.P
Propylene Glycol	B.P
Di- Sodium Hydrogen ortho-phosphate anhydrous	I.H

6.2 Incompatibilities:
Not applicable

6.3 Shelf life:
36 Months

6.4 Special precautions for storage:

Store protected from light and moisture, below 30°c. Do not freeze.

6.5 Nature and contents of container:
30 gm printed lemi tube.

6.6 Special precaution for disposal
No special requirements.

7. Marketing Authorization Holder

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