1.6.1.1 Name of the medicinal Product

KETOCONAZOLE CREAM BP 2% W/W

1.6.1.1.1 strength

2% W/W

1.6.1.1.2 Pharmaceutical Form

Topical Cream

White color smooth cream.

1.6.1.2 Qualitative and Quantitative Composition

1.6.1.2.1 Qualitative declaration

Ketoconazole BP

1.6.1.2.2 Quantitative declaration

Sr. No.	Ingredients	Specification	Label Claim (% w/w)	Reason for Inclusion
1.	Ketoconazole	BP	2.00	Antifungal
2.	Cetosteryl Alcohol	BP	8.00	Viscosity increasing agent
3.	White Soft Paraffin	BP	5.00	Cream Base
4.	Cetomacrogol 1000	BP	2.00	Solubilizing agent
5.	Light Liquid Paraffin	BP	6.00	Emollient
6.	Propylene Glycol	BP	5.00	Humectants
7.	Anhydrous Disodium Hydrogen Phosphate	BP	0.30	Buffering Agent
8.	Disodium Edetate	BP	0.01	Chelating agent
9.	Purified Water	BP	Q.S.	Vehicle

1.6.1.3 Pharmaceutical Form

Topical Cream

1.6.1.4 Clinical Particulars

1.6.1.4.1 Therapeutic Indications

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

1.6.1.4.2 Posology and Method of Administration

Adults:

Tinea pedis: Ketoconazole cream should be applied thinly to the affected areas twice daily. The usual duration of treatment for mild infections is 1 week. For more severe or extensive infections (e.g. involving the sole or sides of the feet), treatment should be continued for 2–3 days after all signs of infection have disappeared to prevent relapse.

For other infections:

Ketoconazole cream should be applied to the affected areas once or twice daily, depending on the severity of the infection.

The treatment should be continued until a few days after the disappearance of all signs and symptoms.

The usual duration of treatment is: tinea versicolor 2–3 weeks, tinea corporis 3–4 weeks.

Seborrheic dermatitis:

Ketoconazole Cream 2% should be applied to the affected area twice daily for four weeks until clinical response is noted.

Elderly: Refer to adult dosing.

1.6.1.4.3 Contraindications

Ketoconazole Cream is contraindicated in patients with a known hypersensitivity to ketoconazole or any component of this product.

1.6.1.4.4 Special Warnings and Special Precautions for Use

Ketoconazole Cream is not for ophthalmic use.

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 Cream in the evening, and to subsequently and gradually withdraw the steroid therapy over a period of 2-3 weeks.

Pregnancy: Pregnancy category C. There are no adequate and well-controlled studies in pregnant women. Ketoconazole should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation: It is not known whether Ketoconazole Cream 2% administered topically could result in sufficient systemic absorption to produce detectable quantities in breast milk. Caution should be exercised when using topically applied Ketoconazole products during lactation

Pediatric Use: Safety and effectiveness in children have not been established.

1.6.1.4.5 Interaction with other medicinal products and other forms of interaction

There are no known significant interactions.

1.6.1.4.6 Fertility, Pregnancy and Lactation

Pregnancy: Pregnancy category C. There are no adequate and well-controlled studies in pregnant women. Ketoconazole should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation: It is not known whether Ketoconazole Cream 2% administered topically could result in sufficient systemic absorption to produce detectable quantities in breast milk. Caution should be exercised when using topically applied Ketoconazole products during lactation.

1.6.1.4.7 Effects on ability To Drive and use Machines

None known.

1.6.1.4.8 Undesirable Effects

Application site pruritus, skin burning sensation, stinging, dryness and headache.

1.6.1.4.9 Overdose

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

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

1.6.1.5 Pharmacological Properties

1.6.1.5.1 Pharmacodynamics Properties

Ketoconazole interferes with biosynthesis of triglycerides and phospholipids by blocking fungal cytochrome P450, thus altering cell membrane permeability in susceptible fungi. It also inhibits other fungal enzymes resulting in the accumulation of toxic concentrations of hydrogen peroxide.

1.6.1.5.2 Pharmacokinetic Properties

Plasma concentrations of ketoconazole were not detectable after topical administration of Ketoconazole Cream 2% in adults on the skin. In one study in infants with seborrhoeic dermatitis (n = 19), where approximately 40 g of Ketoconazole Cream 2% 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.

1.6.1.5.3 Preclinical Safety Data

Not Relevant

1.6.1.6 Pharmaceutical Particulars

1.6.1.6.1 List of Excipients

Cetosteryl Alcohol BP

White Soft Paraffin BP

Cetomacrogol 1000 BP

Light Liquid Paraffin BP

Propylene Glycol BP

Anhydrous Disodium Hydrogen Phosphate BP

Disodium Edetate BP

Purified Water BP

1.6.1.6.2 Incompatibilities

Not applicable.

1.6.1.6.3 Shelf Life

36 months

1.6.1.6.4 Special Precautions for Storage

Store below 30°C. Protect from light. Do not freeze.

1.6.1.6.5 Nature and Contents of Container

White colour smooth cream filled in 15 gm aluminium collapsible tube. Such 1 tube is packed in a printed carton with package insert.

1.6.1.6.6 Special precaution for disposal and other handling

Dispense in a tight, with a child-resistant closure.

1.6.1.7 Marketing Authorization Holder And Manufacturing Site Addresses

1.6.1.7.1 Name and Address of Marketing Authorization Holder

LINCOLN PHARMACEUTICALS LIMITED

Trimul Estate, Khatraj, Tal. Kalol,

Dist. Gandhinagar,

Gujarat, India.

Phone: +91-02764-665000

Telefax: +91-02764-281809

E-mail: info@lincolnpharma.com

Web site: www.lincolnpharma.com

1.6.1.7.2 Name and Address of manufacturing site(s)

LINCOLN PHARMACEUTICALS LIMITED
Trimul Estate, Khatraj, Tal. Kalol,
Dist. Gandhinagar,
Gujarat, India.
Phone: +91-02764-665000
Telefax: +91-02764-281809
E-mail: info@lincolnpharma.com
Web site: www.lincolnpharma.com

1.6.1.8 Marketing Authorization Number

To be included after obtaining first registration.

1.6.1.9 Date of First <Registration> / Renewal of The <Registration>

It will be applicable after registration of this product.

1.6.1.10 Date of Revision of the Text

1.6.1.11 Dosimetry (If Applicable)

Not Applicable

1.6.1.12 Instructions for preparation of radiopharmaceuticals (if Applicable)

Not Applicable