LINCOLN PHARMACEUTICALS LTD.	Artwork No.	MAL-E-PI1-0826	Used Colours	
APPROVED A/W	Size	120 x 145 mm Packing Insert (2 Page) Auto	■	Black
	Folded size	20 x 145 mm		
Revision For/Note	Printout	Fit to page		
	Pack Style	NA		
Party Address Correction	Board	58 GSM Maplitho Paper		
	Coating	NA		
	Work Order No. EXP/SAM/DOM	For Malaysia		
			Supersede to: (Old A/W No.) MAL-E-PI0225	
	Date	20-8-26		

A/W Dept. (Sign & Date)	IRA Dept. (Sign & Date)	QA Dept. (Sign & Date)	Party Approval (Sign & Date)

145.00 mm

KETOCONAZOLE CREAM BP 2 % W/W

KONAZOL

COMPOSITION:
Ketoconazole BP 2% w/w
Excipients Q.S.

EXCIPIENTS: Cetosteryl Alcohol BP, White Soft Paraffin BP, Cetomacrogol 1000, Light Liquid Paraffin BP, Propylene Glycol BP, Disodium hydrogen Phosphate anhydrous BP, Disodium Edetate BP, Purified water BP.

PRODUCT DESCRIPTION: White colour smooth cream.

PHARMACODYNAMICS:
Pharmacotherapeutic group: Antifungal 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.

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.

PHARMACOKINETICS :
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.

INDICATIONS:
Ketoconazole 2% Cream is indicated for topical application in the treatment of dermatophyte infections of the skin: tinea corporis, tinea cruris, tinea manus and tinea pedis due to *Trichophyton rubrum*, *Trichophyton mentagrophytes*, *Microsporum canis* and *Epidermophyton floccosum*, as well as in the treatment of cutaneous candidosis and tinea (pityriasis) versicolor.

Ketoconazole 2% Cream is also indicated for the treatment of seborrhoeic dermatitis, a skin condition associated with the presence of *Malassezia furfur*.

RECOMMENDED DOSAGE:
Dosage
Cutaneous candidosis, tinea corporis, tinea cruris, tinea manus, tinea pedis and tinea (pityriasis) versicolor: it is recommended that Ketoconazole 2% Cream be applied once daily to cover the affected and immediate surrounding area.

Seborrheic dermatitis: Ketoconazole 2% Cream should be applied to the affected area once or twice daily.

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.

The usual initial duration of treatment in seborrheic dermatitis is 2 to 4 weeks. Maintenance therapy is applied once or twice weekly in seborrheic dermatitis.

Treatment should be continued, until a few days after disappearance of all symptoms. The diagnosis should be reconsidered if no clinical improvement is noted after 4 weeks of treatment.

Special populations
Paediatrics
There are limited data on the use of ketoconazole 2% cream in paediatric patients.

Administration
Topical administration to the skin.

ROUTE OF ADMINISTRATION:
Topical

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

WARNINGS AND PRECAUTIONS:
Ketoconazole 2% Cream is not for ophthalmic use.
If coadministered with a topical corticosteroid, to prevent a

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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 2% Cream in the evening, and to subsequently and gradually withdraw the topical corticosteroid therapy over a period of 2 – 3 weeks.

INTERACTIONS WITH OTHER MEDICAMENTS:
No interaction studies have been performed.

PREGNANCY AND LACTATION:
Pregnancy: There are no adequate and well-controlled studies in pregnant women. Plasma concentrations of ketoconazole are not detectable after topical application of Ketoconazole 2% Cream to the skin of non-pregnant humans. There are no known risks associated with the use of Ketoconazole 2% Cream in pregnancy.
Lactation: There are no adequate and well-controlled studies in lactating women. There are no known risks associated with the use of Ketoconazole 2% Cream in lactation.

SIDE EFFECTS
The adverse reactions that were reported for Ketoconazole 2% Cream:

System Organ Class	Adverse Reactions		
	Category		
	Common	Uncommon	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	

SYMPTOMS AND TREATMENT OF 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.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINE:
No data are available regarding the influence of Ketoconazole on a patient's ability to drive or operate machinery.

PRECLINICAL SAFETY DATA :
Not Applicable.

INSTRUCTION FOR USE:
Puncture nozzle seal with piercing point of cap. Replace cap after each use.

STORAGE CONDITION:
Store below 30°C.

SHELF LIFE:
36 months
The product should not be used more than 28 days after opening of the tube.

PRESENTATION:
White colour smooth cream is filled in 15 gm white colour Aluminum Collapsible tube and closed with Crock Wadded White Cap (With Piercing Point). Such 1 tube packed in Printed Carton with Package Insert.

DATE OF REVISION:
21/08/2026

Manufactured by :
LPL LINCOLN PHARMACEUTICALS LTD.
Trimul Estate, Khatraj, Tal-Kalol
382721 Gandhinagar India

Product Registration Holder:
Healol
Healol Pharmaceuticals Sdn. Bhd.
74, 74-1, 74-2, 74-3, Pusat Bandar Wangsa Maju,
Jalan Wangsa Delima 6 (1/27F), Seksyen 5 Wangsa Maju,
53300 Kuala Lumpur, Malaysia.

MAL-E-PI1-0826