

 APPROVED A/W	Artwork No.	MAL-E-PI0826	Used Colours	
	Size	120 x 145 mm Packing Insert (Auto) 2 Pages		Black
Revision For/Note New A/W	Folded size	20 x 145 mm (3 Fold 6 Flap)		
	Printout	Fit to page		
	Pack Style	NA		
	Board	58 GSM Maplitho Paper		
	Coating	NA		
	Work Order No. EXP/SAM/DOM	For Malaysia	Supersede to: (Old A/W No.)	
	Date	21-8-26		
A/W Dept. (Sign & Date)		IRA Dept. (Sign & Date)	QA Dept. (Sign & Date)	Party Approval (Sign & Date)

145.00 mm

CLOTRILIN
CLOTRIMAZOLE CREAM BP 1% W/W

COMPOSITION:
Clotrimazole BP 1% w/w
Cream Base Q.S.

EXCIPIENTS: Methyl Hydroxy benzoate BP, Propyl Hydroxy benzoate BP, Cetosteryl Alcohol BP, Cetomacrogol 1000, Light Liquid Paraffin BP, White Soft Paraffin BP, Phosphoric Acid BP, Sodium Hydroxide BP, Purified Water BP.

PRODUCT DESCRIPTION: A White colour smooth cream.

PHARMACODYNAMICS:
Pharmacotherapeutic group: Antifungals for topical use – imidazole and triazole derivatives.
ATC Code: D01AC01

Clotrimazole acts against fungi by inhibiting ergosterol synthesis. Inhibition of ergosterol synthesis leads to structural and functional impairment of the fungal cytoplasmic membrane.

Clotrimazole has a broad antimycotic spectrum of action in vitro and in vivo, which includes dermatophytes, yeasts, moulds, etc.

Under appropriate test conditions, the MIC values for these types of fungi are in the region of less than 0.062-8.0 µg/ml substrate. The mode of action of clotrimazole is primarily fungistatic or fungicidal depending on the concentration of clotrimazole at the site of infection. In vitro activity is limited to proliferating fungal elements; fungal spores are only slightly sensitive.

In addition to its antimycotic action, clotrimazole also acts on gram-positive microorganisms (Streptococci /Staphylococci / Gardnerella vaginalis), and gram-negative microorganisms (Bacteroides).

In vitro clotrimazole inhibits the multiplication of Corynebacteria and gram-positive cocci - with the exception of Enterococci - in concentrations of 0.5-10 µg/ml substrate.

Primarily resistant variants of sensitive fungal species are very rare; the development of secondary resistance by sensitive fungi has so far only been observed in very isolated cases under therapeutic conditions.

PHARMACOKINETIC:
Pharmacokinetic investigations after dermal application have shown that clotrimazole is minimally absorbed from the intact or inflamed skin into the human blood circulation. The resulting peak serum concentrations of clotrimazole were below the detection limit of 0.001 mcg/ml, suggesting that clotrimazole applied topically is unlikely to lead to measurable systemic effects or side effects.

INDICATIONS:
Clotrimazole 1% cream is recommended for the treatment of:
All dermatomycoses due to moulds and other fungi (e.g. trichophyton species).
All dermatomycoses due to yeasts (candida species).
Skin diseases showing secondary infection with these fungi.
Candidal nappy rash, vulvitis and balanitis.

RECOMMENDED DOSE:
Adults
The cream should be applied thinly 2-3 times daily and rubbed in gently. A strip of cream (½ cm long) is enough to treat an area of about the size of the hand. Treatment should be continued for at least one month for dermatophyte infections and at least two weeks for candidal infections. If the feet are infected they should be washed and dried, especially between the toes, before applying the clotrimazole 1% cream.
Elderly
Refer to adult dosing.

ROUTE OF ADMINISTRATION:
Topical

CONTRAINDICATIONS:
Hypersensitivity to clotrimazole or any other ingredient in this medicine. Do not use the cream to treat nail or scalp infections.

WARNINGS AND PRECAUTIONS:
Jauhkan daripada capaian kanak-kanak / Keep out of reach of children
***Please consult your pharmacist/doctor before**

120.00 mm

7 pt Times New Roman

using this product'

Topical: When using topical formulation, avoid contact with eyes. Do not use the clotrimazole 1% cream to treat nail or scalp infections.

Patient should take special precaution for using the clotrimazole 1% cream as it contains methyl hydroxybenzoate, propyl hydroxybenzoate may cause allergic reactions (possibly delayed) and cetostearyl alcohol, which may cause local skin reactions (e.g. contact dermatitis).

INTERACTION WITH OTHER MEDICAMENTS:

Laboratory tests have suggested that, when used together, this product may cause damage to latex contraceptives. Consequently, the effectiveness of such contraceptives may be reduced. Patients should be advised to use alternative precautions for at least five days after using this product.

PREGNANCY AND LACTATION:

Pregnancy: There is a limited amount of data from the use of clotrimazole in pregnant women. Clotrimazole can be used during pregnancy, but only under the supervision of a physician or midwife.

Lactation: It is not known whether this drug is excreted in human milk, caution should be exercised when clotrimazole is used by a nursing woman.

SIDE EFFECTS:

As the listed side effects are based on spontaneous reports, assigning an accurate frequency of occurrence for each is not possible. Immune system disorders: allergic reaction (syncope, hypotension, dyspnea, urticaria). Skin and subcutaneous tissue disorders: blisters, discomfort/pain, oedema, erythema, irritation, peeling/exfoliation, pruritus, rash, stinging/burning.

SYMPTOMS AND TREATMENT OF OVERDOSE:

No risk of acute intoxication is seen as it is unlikely to occur following a single dermal application of an overdose (application over a large area under conditions favourable to absorption) or inadvertent oral ingestion. There is no specific antidote.

However, in the event of accidental oral ingestion, gastric lavage is rarely required and should be considered only if a life-threatening amount of

Clotrimazole has been ingested within the preceding hour or if clinical symptoms of overdose become apparent (e.g. dizziness, nausea or vomiting). Gastric lavage should be carried out only if the airway can be protected adequately.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINE:

Clotrimazole cream has no or negligible influence on the ability to drive or use machines.

PRECLINICAL SAFETY DATA:

Not Applicable.

INSTRUCTION FOR USE:

For External Use Only

To open the tube, unscrew the cap. Then pierce the seal of the tube with the pin on the top of the cap.

STORAGE CONDITION :

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

SHELF LIFE:

36 months

The product should not be used more than 28 days after the opening of the tube.

PRESENTATION:

A 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.

Manufactured by :



Trimul Estate, Khatraj, Tal-Kalol
382721 Gandhinagar, Gujarat, 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.

DATE OF REVISION: 21/08/2026

MAL-EP0826