

apex	apex laboratories private limited	Date : 16.07.2026
Title:	Erbinox Cream Pack Insert (Malaysia)	AWC :

Size: 120 x 80 mm

Cover & Back Cover

Erbinox

Terbinafine Hydrochloride Cream 1% w/w

FOR EXTERNAL USE ONLY

NAME AND STRENGTH OF ACTIVE SUBSTANCE(S)
Terbinafine Hydrochloride BP 1 % w/w

PRODUCT DESCRIPTION:
Erbinox cream is a white to off-white cream.

PHARMACODYNAMICS:
Terbinafine Hydrochloride inhibits ergosterol synthesis by inhibiting squalene epoxidase, an enzyme that is part of the fungal cell membrane synthesis pathway, since Terbinafine prevents conversion of squalene to lanosterol, ergosterol cannot be synthesized. This is thought to cell membrane permeability, causing fungal cell lysis. The chitosan demonstrates blood clotting, film forming, wound healing and skin restoration properties.

PHARMACOKINETICS:
Pharmacokinetic studies have demonstrated persistent concentrations well above the minimum inhibitory concentration for the common dermatophytes 7 days after topical application. Percutaneous absorption occurs following topical application of the cream. Systemically absorbed drug is extensively metabolized. Approximately 75 % of cutaneously absorbed drug is eliminated in urine, principally as metabolites. Half-life when absorbed through skin is approximately 21 hours.

INDICATIONS:
Erbinox cream is indicated for:

- Athlete's foot

- Ringworm
- Jock itch

RECOMMENDED DOSE:
Apply a thin layer to the affected area 1-2 times daily, generally for 1-2 weeks. It is generally only for adults and children above 12 years old. Not recommended for children below 12 years old.

ROUTE OF ADMINISTRATION:
Topical

CONTRAINDICATIONS:
Erbinox cream must not be used in patients with hypersensitivity to any of the ingredients.

WARNING AND PRECAUTIONS:
Erbinox cream is for EXTERNAL USE only. Avoid contact with eyes.

INTERACTIONS WITH OTHER MEDICAMENTS:
There are no known drug interactions with Erbinox Cream.

PREGNANCY & LACTATION:
PREGNANCY:
For terbinafine, no clinical data on exposed pregnancies are available. Animal studies do not indicate any harmful effects with respect to pregnancy or the health of the foetus. It is not appropriate for use Erbinox cream during pregnancy unless clearly necessary.

LACTATION:
Terbinafine is excreted into breast-milk. After topical use, only a low systemic exposure is expected. Terbinafine should only be used in a nursing mother if the expected benefit justifies the risk to the infant. In addition, infants must not be allowed to come into contact with any treated skin, including the breast.

SIDE EFFECTS:
Adverse reactions are listed below by system organ class and frequency. Frequencies are defined as: 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), or not known (cannot be estimated from available data). Adverse reactions identified during post-marketing use are reported voluntarily from a

 Red  Black

Inside Spread

population of uncertain size, the frequency of these reactions is not known but likely to be rare or very rare. Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.

IMMUNE SYSTEM DISORDERS:
Not known: Hypersensitivity.

EYE DISORDERS:
Rare: Eye irritation.

SKIN AND SUBCUTANEOUS TISSUE DISORDERS:
Common: Skin exfoliation, pruritus.
Uncommon: Skin lesion, scab, skin disorder, pigmentation disorder, erythema, skin burning sensation.
Rare: Dry skin, dermatitis contact, eczema.
Not known: Rash.

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS:
Uncommon: Pain, application site pain, application site irritation.
Rare: Condition aggravated.

SYMPTOMS AND TREATMENT OF OVERDOSE:
Symptoms/signs of overdose following ingestion may include headache, nausea, epigastric pain and dizziness.
Further management should be as clinically indicated or as recommended by the national poisons centres where available.

EFFECTS ON ABILITY TO DRIVE & USE MACHINE:
None known.

STORAGE CONDITIONS :
Store at a temperature below 30° C.

DOSAGE FORMS AND PACKAGING AVAILABLE:
DOSAGE FORMS : Topical
PACKAGING AVAILABLE:
Erbinox cream is available in collapsible aluminium tube internally coated with epoxy based lacquer, with polypropylene cap of 15g in an attractive carton.

Preservative used : Benzyl Alcohol BP 1% w/w
Must not be used in patients with hypersensitivity to terbinafine.



Manufactured by:
apex laboratories private limited
B-23 (Plant 1), SIDCO Pharmaceutical Complex,
Alathur-603110, Kancheepuram District, INDIA.

Product registration holder
Unimed Sdn. Bhd.
No 53, Jalan Tembaga SD 5/2B,
Bandar Sri Damansara, 52200,
Kuala Lumpur, Malaysia

Date of revision
16/07/2026

MAIL No: MAL26076015X

120 mm

80 mm

Initiated by	Reviewed by				Approved by
PMT/Design	RA	R&D	Production	QC	QA
Date					