

FIRST AID RESEARCH ANTIFUNGAL CREAM 1OZ- clotrimazole cream

First Aid Research Corp.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Active ingredient	Purpose
Clotrimazole 1%.....	Antifungal

Uses

- cures most athlete's foot, jock itch, and ringworm
- relieves itching, burning, cracking, scaling, and discomfort which accompany these conditions

Warnings

For external use only

Do not use on children under 2 years of age unless directed by a doctor

When using this product avoid contact with the eyes

Stop use and ask a doctor if

- irritation occurs
- there is no improvement within 4 weeks (for athlete's foot and ringworm) or 2 weeks (for jock itch)

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately

Directions

- wash affected area and dry thoroughly
- apply a thin layer over affected area twice daily (morning and night)
- supervise children in the use of this product
- for athlete's foot: pay special attention to spaces between the toes; wear well-fitting, ventilated shoes and change shoes and socks at least once daily
- for athlete's foot and ringworm, use daily for 4 weeks; for jock itch, use daily for 2 weeks
- if condition persists longer, ask a doctor
- this product is not effective on the scalp or nails

Other information

- store between 20° to 25°C (68° to 77°F)
- Lot No. & Exp. Date: see box or see crimp of tube

Inactive ingredients

2-octyldodecanol, benzyl alcohol, cetearly alcohol, cetyl esters, monobasic sodium phosphate dihydrate, polysorbate 60, propylene glycol, purified water, sorbitan stearate

Distributed by:

First Aid Research Corp.

Wantagh, NY 11793 USA

Made in Korea



FIRST AID RESEARCH ANTIFUNGAL CREAM 1OZ

clotrimazole cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75983-464
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLOTRIMAZOLE (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65)	CLOTRIMAZOLE	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CETYL ESTERS WAX (UNII: D072FFP9GU)	
SODIUM PHOSPHATE, MONOBASIC, DIHYDRATE (UNII: 5QWK665956)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
PEG-60 SORBITAN STEARATE (UNII: 073G38N8GC)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75983-464-28	1 in 1 CARTON		
1		28 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	10/14/2014	

Labeler - First Aid Research Corp. (089405927)

Revised: 10/2014

First Aid Research Corp.