

APTRIMAZOLE 1.0% ANTIFUNGAL CREAM- clotrimazole cream
A P J Laboratories Limited

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.

CLOTRIMAZOLE

Antifungal

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

Cures most athlete's foot, jock itch, and ringworm.

Relieves itching, burning, cracking, scaling and discomfort which accompany these conditions.

Do not use:

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

Avoid contact with eyes.

For athlete's foot and ringworm - if irritation occurs, or if there is no improvement within 4 weeks, discontinue use and consult a doctor.

For jock itch - if irritation occurs, or if there is no improvement within two weeks, discontinue use and consult a doctor.

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

Direction:

Clean the affected area and dry thoroughly. Apply a layer of cream over affected area twice daily (morning and night) or as directed by a doctor.

Supervise children in the use of this product.

For athlete's foot, pay special attention to spaces between 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 conditions persist longer, consult a doctor.

This product is not effective on scalp or nails.

PETROLATUM
 LIGHT MINERAL OIL
 CETOSTEARYL ALCOHOL
 EDETIC ACID
 CHLOROCRESOL
 SODIUM PHOSPHATE, DIBASIC, ANHYDROUS
 POLYSORBATE 60
 CETETH-20

DISPLAY PANEL



APTRIMAZOLE 1.0% ANTIFUNGAL CREAM

clotrimazole cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46084-081
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLOTRIMAZOLE (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65)	CLOTRIMAZOLE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
EDETIC ACID (UNII: 9G34HU7RV0)	
CHLOROCRESOL (UNII: 36W5307109)	

SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
CETETH-20 (UNII: I835H2IHHX)	

Product Characteristics

Color	white (offwhite)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46084-081-31	15 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	04/27/2013	

Labeler - A P J Laboratories Limited (677378339)

Registrant - A P J Laboratories Limited (677378339)

Establishment

Name	Address	ID/FEI	Business Operations
A P J Laboratories Limited		677378339	manufacture(46084-081)