

ASTONEA CLOTRIMAZOLE 1% ATHLETES FOOT- clotrimazole cream
ASTONEA LABS PRIVATE 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.

Astonea Clotrimazole USP, 1%

Drug Facts

Active ingredient

Clotrimazole 1% (w/w)

Purpose

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 eyes.

Stop use and ask a doctor if

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

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

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 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° - 25°C (68° - 77°F)
- see carton or tube crimp for lot number and expiration date

Inactive ingredients

Ceteth-20, Cetostearyl Alcohol, Chorocresol, Edetate Disodium, Light Mineral Oil, Propylene Glycol, Sodium Metabisulfite, Water

Principal Display Panel



ASTONEA CLOTRIMAZOLE 1% ATHLETES FOOT			
clotrimazole cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77338-312
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
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CETETH-20 (UNII: I835H2IHHX)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
WATER (UNII: 059QF0KO0R)	
CHLOROCRESOL (UNII: 36W5307109)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77338-312-44	28.3 g in 1 TUBE; Type 0: Not a Combination Product	03/04/2020	
2	NDC:77338-312-48	113 g in 1 TUBE; Type 0: Not a Combination Product	03/04/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	03/04/2020	

Labeler - ASTONEA LABS PRIVATE LIMITED (878533295)

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