

CLOTRIMAZOLE- clotrimazole cream
The IBN SINA Pharmaceutical Industry Ltd.

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 Cream 1%

Drug Facts

Active ingredient

Clotrimazole 1%

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 except under the advice and supervision of 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 (1-800-222-1222) right away.

Directions

- wash the 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 the spaces between the toes
 - wear well-fitting ventilated shoes
 - 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, consult a doctor
- this product is not effective on the scalp or nails

Other information

- store at 2° - 30° C (36° - 86° F)
- Lot No. & Exp. Date: see box or see crimp of tube

Inactive ingredients

cetostearyl alcohol, methylparaben, mineral oil, paraffin, polyoxyl 40 hydrogenated castor oil, polysorbate 80, water

Questions?

Call **1-833-IBN-SINA (1-833-426-7462)**

Manufactured by:

The **IBN SINA** Pharmaceutical Industry Ltd.

Holding # A-80, Ward # 9, Shafipur, Kaliakoir

Gazipur-1751 Bangladesh

www.ibnsinapharma.com

Product of Bangladesh

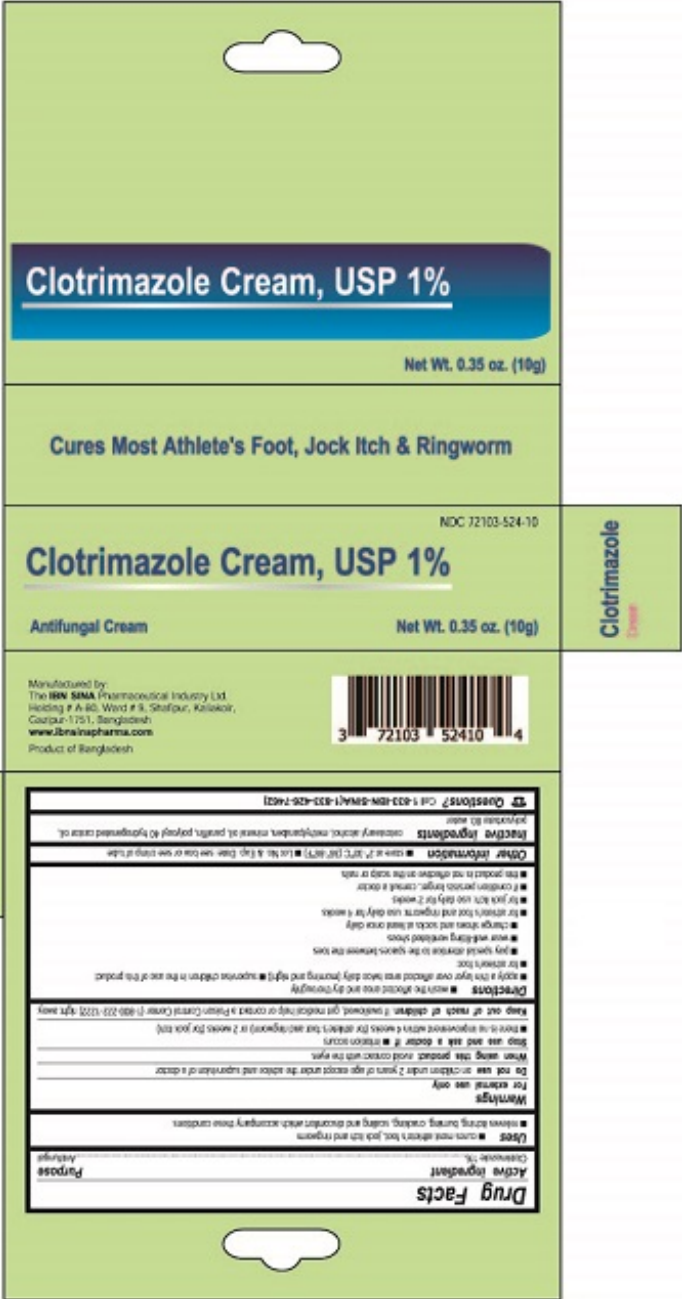
NDC 72103-524-10

Clotrimazole Cream, USP 1%

Antifungal Cream

Net Wt. 0.35 oz (10g)

Cures Most Athlete's Foot, Jock Itch & Ringworm



CLOTRIMAZOLE

clotrimazole cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72103-524
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
METHYLPARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
PARAFFIN (UNII: I9O0E3H2ZE)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72103-524-10	1 in 1 CARTON	03/14/2019	
1		10 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	03/14/2019	

Labeler - The IBN SINA Pharmaceutical Industry Ltd. (731557752)

Establishment

Name	Address	ID/FEI	Business Operations
The Ibn Sina Pharmaceutical Industry Ltd.		731557752	manufacture(72103-524)

Revised: 3/2019

The IBN SINA Pharmaceutical Industry Ltd.