

**JOCK ITCH- 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.*

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**Jock Itch Cream**

***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](http://www.ibnsinapharma.com)**

Product of Bangladesh

NDC 72103-525-10

**Jock Itch Cream**

**Clotrimazole Cream, USP 1%**

**Antifungal Cream**

**Net Wt. 0.35 oz (10g)**

Cures Most Jock Itch

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Manufactured by:  
The IBN SINA Pharmaceutical Industry Ltd.  
Building # A-80, Ward # 3, Shafigpur, Kalkata,  
Gazipur-1731, Bangladesh  
www.ibnsinapharma.com  
Product of Bangladesh



Jock Itch Cream  
Clotrimazole Cream

Lot No. :  
Exp. :

**Drug Facts**

**Active Ingredient**  
Clotrimazole 1%  
*Antifungal*

**Uses**  
■ Cures most athletes' 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:  
■ Dry socks and change them at least once daily.  
■ 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°-8°C (36°-68°F) ■ Lot No. & Exp. Date: see box or see climp of tube  
■ Contains: alcohol, methylparaben, mineral oil, paraffin, polyoxy 40 hydrogenated castor oil, polyoxyl 80, water.

**Inactive Ingredients**

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

## JOCK ITCH

clotrimazole cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72103-525
<b>Route of Administration</b>	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: 059QF0KO0R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72103-525-10	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(72103-525)

Revised: 3/2019

The IBN SINA Pharmaceutical Industry Ltd.