HUA TUO XIAN GAO- clotrimazole ointment SHANGHAI SONGHUA PHARMACEUTICAL CO 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.

DRUG FACTS

Active ingredient

Clotrimazole 1.0%

Purpose

Antifungal

Uses

For the cure of: athlete's foot jock itch ringworm

Relieves:

itching

scaling

cracking

burning

discomfort

soreness

irritation

redness

Warnings

For external use only

Do not use

on children under 12 years of age unless directed by a doctor if pregnant if nursing

When using this product

avoid contact with the eyes do not use the following on the skin: soap alcohol hydrogen peroxide iodine or sulphur compounds

Stop use and ask a doctor if

irritation occurs there is no improvement within 2 weeks when used for jock itch 4 weeks when used for athlete's foot or ringworm

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Adults and children 12 years of age or older:

Wash the affected area and dry thoroughly. In areas where the skin is thickened, soak in warm water to soften it first

Apply a thin layer of the product over the affected area twice daily (morning and night) or as directed by a doctor.

For athlete's foot:

Pay special attention to spaces between the toes. It is useful to apply at night on cotton balls wedged 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.

Children under 12 years: Do not use unless directed by a doctor

Other information

keep container tightly closed store between 2° and 30° C (36° to 86° F)

Inactive ingredients

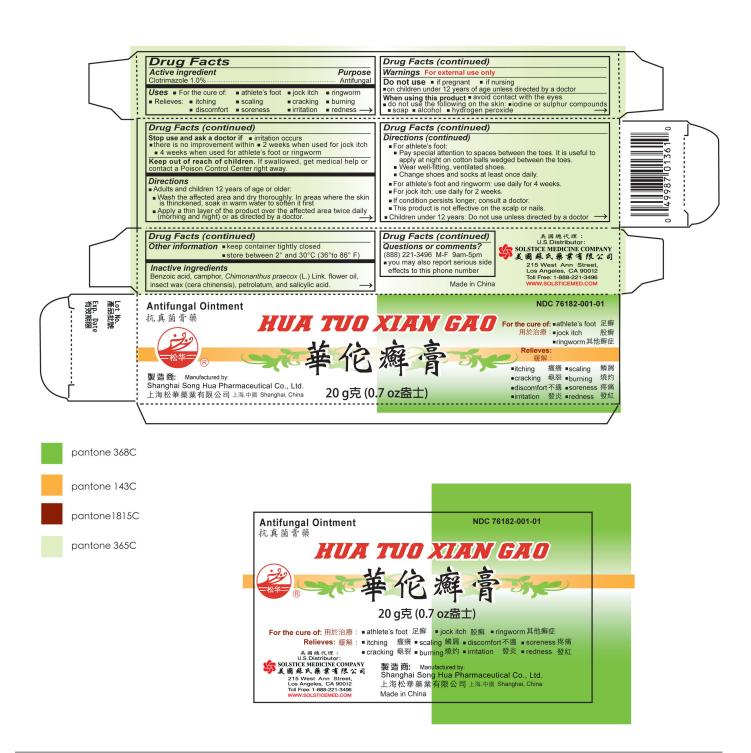
Benzoic acid, camphor, Chimonanthus praecox (L.) Link. flower oil, insect wax (cera chinensis), petrolatum, and salicylic acid.

Questions or comments?

(888) 221-3496 M-F 9am-5pm

you may also report serious side effects to this phone number

HUA TUO XIAN GAO Antifungal Ointment NDC 76182-001-01 20 g (0.7 oz)



HUA TUO XIAN GAO

clotrimazole ointment

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76182-001
Route of Administration	TOPICAL		

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

Inactive Ingredients			
Ingredient Name	Strength		
BENZOIC ACID (UNII: 8 SKN0 B0 MIM)			
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)			
PETROLATUM (UNII: 4T6H12BN9U)			
SALICYLIC ACID (UNII: O414PZ4LPZ)			

Packaging				
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:76182-001-01	20 g in 1 TUBE; Type 0: Not a Combination Product	04/28/2011	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part333C	04/28/2011		

Labeler - SHANGHAI SONGHUA PHARMACEUTICAL CO LTD (420355463)

Establishment				
Name	Address	ID/FEI	Business Operations	
SHANGHAI SONGHUA PHARMACEUTICAL CO LTD		420355463	manufacture (76 18 2-0 0 1)	

Revised: 10/2018 SHANGHAI SONGHUA PHARMACEUTICAL CO LTD