

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)

<p>Drug Facts Active ingredient Clotrimazole 1.0% Purpose Antifungal</p> <p>Uses ■ For the cure of: ■ athlete's foot ■ jock itch ■ ringworm ■ Relieves: ■ itching ■ scaling ■ cracking ■ burning ■ discomfort ■ soreness ■ irritation ■ redness →</p>	<p>Drug Facts (continued) Warnings For external use only Do not use ■ if pregnant ■ if nursing ■ on children under 12 years of age unless directed by a doctor When using this product ■ avoid contact with the eyes ■ do not use the following on the skin: ■ iodine or sulphur compounds ■ soap ■ alcohol ■ hydrogen peroxide →</p>
<p>Drug Facts (continued) 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. →</p>	<p>Drug Facts (continued) Directions (continued) ■ 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 →</p>
<p>Drug Facts (continued) Other information ■ keep container tightly closed ■ store between 2° and 30°C (36°to 86° F) Inactive ingredients Benzoic acid, camphor, <i>Chimonanthus praecox</i> (L.) Link. flower oil, insect wax (<i>cera chinensis</i>), petrolatum, and salicylic acid. →</p>	<p>Drug Facts (continued) Questions or comments? (888) 221-3496 M-F 9am-5pm ■ you may also report serious side effects to this phone number Made in China</p> <p>美國總代理： U.S. Distributor: SOLSTICE MEDICINE COMPANY 美國蘇氏藥業有限公司 215 West Ann Street, Los Angeles, CA 90012 Toll Free: 1-888-221-3496 WWW.SOLSTICEMED.COM</p>



LOT No. 產品批號
 Exp. Date 有效期限

Antifungal Ointment
 抗真菌膏藥

HUA TUO XIAN GAO

華佗癬膏

製造商: Manufactured by:
 Shanghai Song Hua Pharmaceutical Co., Ltd.
 上海松華藥業有限公司 上海, 中國 Shanghai, China

20 克 (0.7 oz 盎司)

NDC 76182-001-01

For the cure of: ■ athlete's foot 足癬
 用於治療: ■ jock itch 股癬
 ■ ringworm 其他癬症

Relieves:
 緩解: ■ itching 瘙癢 ■ scaling 鱗屑
 ■ cracking 龜裂 ■ burning 燒灼
 ■ discomfort 不適 ■ soreness 疼痛
 ■ irritation 發炎 ■ redness 發紅

- pantone 368C
- pantone 143C
- pantone 1815C
- pantone 365C

Antifungal Ointment
 抗真菌膏藥

NDC 76182-001-01

HUA TUO XIAN GAO

華佗癬膏

20 克 (0.7 盎司)

For the cure of: 用於治療: ■ athlete's foot 足癬 ■ jock itch 股癬 ■ ringworm 其他癬症

Relieves: 緩解: ■ itching 瘙癢 ■ scaling 鱗屑 ■ discomfort 不適 ■ soreness 疼痛
 ■ cracking 龜裂 ■ burning 燒灼 ■ irritation 發炎 ■ redness 發紅

美國總代理:
 SOLSTICE MEDICINE COMPANY
 美國蘇氏藥業有限公司
 215 West Ann Street,
 Los Angeles, CA 90012
 Toll Free: 1-888-221-3496
 WWW.SOLSTICEMED.COM

製造商: Manufactured by:
 Shanghai Song Hua Pharmaceutical Co., Ltd.
 上海松華藥業有限公司 上海, 中國 Shanghai, China
 Made in China

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: 8SKN0B0MM)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
PETROLATUM (UNII: 4T6H12BN9U)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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(76182-001)

Revised: 10/2018

SHANGHAI SONGHUA PHARMACEUTICAL CO LTD