

HUA TUO XIAN GAO ANTIFUNGAL- clotrimazole ointment
MADISON ONE ACME INC

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

- 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:
 - 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 flower oil, petrolatum, salicylic acid, and yellow wax.

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

Clotrimazole 1.0%

Cure Athlete's Foot Jock Itch & Ringworm

NDC 55614-650-01

20 g (0.7 oz)

Odorless

Non-Greasy



FOIL

Pantone
348CPantone
368CPantone
032CPantone
143C

Black

HUA TUO XIAN GAO ANTIFUNGAL

clotrimazole ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55614-650
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
BENZOIC ACID (UNII: 8SKN0B0MIM)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
CHIMONANTHUS PRAECOX FLOWER OIL (UNII: EB4HIB5MLF)	
PETROLATUM (UNII: 4T6H12BN9U)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
YELLOW WAX (UNII: 2ZA36H0S2V)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55614-650-01	1 in 1 BOX	04/01/2020	
1		20 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 mono graph final	part333C	04/01/2020	

Labeler - MADISON ONE ACME INC (096196758)**Establishment**

Name	Address	ID/FEI	Business Operations
Zhejiang Dingtai Pharmaceutical Co., Ltd		420598724	manufacture(55614-650)

