

AU KAH CHUEN FUGICAL- calamine and diphenhydramine hydrochlorid cream
Zhejiang Dingtai 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

Calamine 10%

Diphenhydramine hydrochloride 2%

Purpose

Skin protectant

External analgesic

Uses

For the temporary relief of pain, itching, and rushes due to:

poison ivy

poison oak

poison sumac

Dries the oozing and weeping of:

poison ivy

poison oak

poison sumac

Warnings

For external use only

When using this product □

avoid contact with the eyes

Stop use and ask a doctor if □

conditions worsens

condition does not improve within 7 days

symptoms clear up and occur again within a few days

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Adults and children 2 years of age or older: Apply liberally to affected area not more than 3 to 4 times daily.

Children under 2 years: Do not use, consult a doctor

Other information

keep tightly sealed

Inactive ingredients Alcohol, camphor, ceteth-20, cetostearyl alcohol, light mineral oil, menthol, methylparaben, petrolatum, propylparaben, silicon dioxide and water.

Questions or comments? (888) 221-3496 M-F 9am-5pm
you may also report serious side effects to this phone number

Au Kah Chuen Fugical Cream

Calamine 10%

Diphenhydramine hydrochloride 2%

External Analgesic and Poison Ivy, Oak, and Sumac Drying Cream

Net Wt. 0.5 oz (15 g)

NDC 69070-306-01

Au Kah Chuen Fugical Cream
 歐家全膚適軟膏 外盒
 Size: 32mm x 25mm x 117mm

06/03/2019



calamine and diphenhydramine hydrochlorid cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69070-306
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Zinc Oxide (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	9.95 g in 100 g
FERRIC OXIDE RED (UNII: 1K09F3G675) (FERRIC OXIDE RED - UNII:1K09F3G675)	FERRIC OXIDE RED	0.05 g in 100 g
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
CETETH-20 (UNII: I835H2IHHX)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
MENTHOL (UNII: L7T10EIP3A)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PETROLATUM (UNII: 4T6H12BN9U)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69070-306-01	1 in 1 BOX	06/10/2019	
1		15 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	part347	06/10/2019	

Labeler - Zhejiang Dingtai Pharmaceutical Co., Ltd (420598724)

Establishment

Name	Address	ID/FEI	Business Operations
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Revised: 6/2019

Zhejiang Dingtai Pharmaceutical Co., Ltd