FAMILY CARE ANTI-ITCH - diphenhydramine hydrochloride cream
TAI GUK PHARM. 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 Ingredients Purpose

Diphenhydramine Hydrochloride USP, 1%.....Antihistamine

Zinc acetate, 0.1%.....Skin Protectant

Uses

- for the temporary relief of itching and pain associated with minor skin irritations and rashes due to insect bites, poison ivy, poison oak, poison sumac
- dries the oozing and weeping of poison ivy, poison oak and poison sumac

For external use only

Do not use

- on chicken pox, measles, blisters or on extensive areas of the skin
- any other drug containing diphenhydramine while using this product

When using this product avoid contact with the eyes

Stop use and ask a doctor if condition worsens, or if symptoms persist for more than 7 days, or 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 12 years of age and older, apply to affected area not more than 3 to 4 times daily, or as directed by a doctor
- children under 12 years of age, consult a doctor
- do not use with any other product containing diphenhydramine, even one taken by mouth
- discontinue use and consult a physician if rash or irritation develops

Other information

- store at room temperature
- Lot No. and Exp. Date: see box or see crimp of tube

Inactive ingredients

Propylene Glycol, Cetanol, Polyoxyl 40 Stearate, Stearyl Alcohol, Methylparaben, Propylparaben, Purified Water

Distributed by:

Consumer Care Products Corp.

Cerritos, CA 90703 USA

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FAMILY CARE ANTI-ITCH

diphenhydramine hydrochloride cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68169-0049
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	10 mg in 1 g
ZINC ACETATE (UNII: FM5526K07A) (ZINC - UNII:J41CSQ7QDS)	ZINC ACETATE	1 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYOXYL 40 STEARATE (UNII: 13A4J4NH9I)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:68169-0049-5	1 in 1 CARTON		
1		28 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/16/2010	

Labeler - TAI GUK PHARM. CO., LTD. (631101656)

Revised: 4/2010 TAI GUK PHARM. CO., LTD.