

WESTERN FAMILY ITCH RELIEF - diphenhydramine hydrochloride, zinc acetate cream
Western Family Food, 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 ingredients	Purpose
Diphenhydramine Hydrochloride 2%.....	Topical analgesic
Zinc acetate 0.1%.....	Skin protectant

Uses temporarily relieves pain and itching associated with:

- insect bites
- minor burns
- sunburn
- minor skin irritations
- minor cuts
- scrapes
- rashes due to poison ivy, poison oak and poison sumac
- Dries the oozing and weeping of poison ivy, poison oak, and poison sumac

Warnings For external use only.

Do not use

- on large areas of the body
- with any other product containing diphenhydramine, even one taken by mouth

Ask a doctor before use

- on chicken pox
- on measles

When using this product

- avoid contact with eyes

Stop use and ask a doctor if

- condition worsens or does not improve within 7 days
- 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.

Directions

- do not use more than directed
- adults and children 2 years of age and older: apply to affected area no more than 3 to 4 times daily
- children under 2 years of age: ask a doctor

Other information

- store between 20°C and 25°C (68°F and 77°F)

Inactive ingredients cetyl alcohol, diazolidinyl urea, methylparaben, polyethylene glycol monostearate 1000, propylene glycol, propylparaben, and purified water

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Western Family Foods, Inc.
P.O. Box 4057
Portland, OR 97208 U.S.A.
Made in Korea



WESTERN FAMILY ITCH RELIEF
diphenhydramine hydrochloride, zinc acetate cream

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55312-053	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	2 g in 100 g		
ZINC ACETATE (UNII: FM5526K07A) (ZINC CATION - UNII:13S1S8SF37)	ZINC ACETATE ANHYDROUS	0.1 g in 100 g		
Inactive Ingredients				
Ingredient Name	Strength			
CETYL ALCOHOL (UNII: 936JST6JCN)				
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)				
METHYL PARABEN (UNII: A2I8C7HI9T)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
PROPYL PARABEN (UNII: Z8IX2SC1OH)				
WATER (UNII: 059QF0K00R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55312-053-28	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	04/30/2013		

Labeler - Western Family Food, Inc. (192166072)

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Western Family Food, Inc.