

ITCH RELIEF CREAM- zinc acetate 0.1%, diphenhydramine hydrochloride 2% cream

Pharmacy Value Alliance LLC

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.

Itch Relief Cream

Drug Facts

Active Ingredient

Diphenhydramine Hydrochloride 2%

Purpose

Topical Analgesic

Active Ingredient

Zinc Acetate 0.1%

Purpose

Skin Protectant

Uses

For the temporary relief from pain and itching associated with:

- insect bites
- minor burns
- sunburn
- minor skin irritation
- minor cuts
- rashes due to poison ivy, poison oak, and poison sumac
- dries weeping and oozing of poison ivy, oak, and sumac

Warnings

For External Use only

Do not use on large areas of the body or with any other product containing diphenhydramine, even one taken by mouth

Ask a doctor before use if you have chicken pox or measles

When using this product avoid contact with eyes.

Stop Use and ask a doctor if

- Conditions worsen or do 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 the reach of children.

If swallowed, get medical help or contact Poison Control Center immediately

Directions

- Do not use more than directed
- Adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily
- Children under 2 years of age: consult a doctor

Other Information

- Store at controlled room temperature 20°-25°C (68°-77°F)
- Close cap tightly after use

Inactive Ingredients

Aloe Vera (Aloe Barbadensis), leaf juice, Cetyl alcohol, Glyceryl monostearate, Methylparaben, Mineral Oil, Petrolatum, Polyoxyethylene, lauryl ether, Propylene glycol, Propylparaben, Purified Water, Stearic acid

Itch Relief Cream

Antihistamine Topical Analgesic Skin Protectant

Temporarily relieves the itching and pain associated with:

- insect bites
- allergic itch
- skin irritations

Distributed By:

Pharmacy Value Alliance, LLC.

407 East Lancaster Avenue

Wayne, PA. 19087

www.emersongroup.com

Product of PRC

Packaging



ITCH RELIEF CREAM			
zinc acetate 0.1%, diphenhydramine hydrochloride 2% cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-163
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	0.1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
METHYLPARABEN (UNII: A2I8C7HI9T)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PETROLATUM (UNII: 4T6H12BN9U)	
LAURETH-23 (UNII: N72LMW566G)	
WATER (UNII: 059QF0KO0R)	
MINERAL OIL (UNII: T5L8T28FGP)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-163-01	1 in 1 BOX	09/01/2016	
1		28 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	07/19/2016	

Labeler - Pharmacy Value Alliance LLC (101668460)

Registrant - Trifecta Pharmaceuticals USA (079424163)