ANTI ITCH- diphenhydramine hcl, zinc acetate cream Kareway Product, 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.

Pure-Aid Anti-Itch Cream

Active ingredients (in each gram)

Diphenhydramine HCI 2%

Zinc acetate 0.1%

Purposes

Topical analgesic

Skin protectant

Uses

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

Warnings

For external use only

Do not use

- on chicken pox or measles
- with any other product containing diphenhydramine, even one taken by mouth
- on large areas of the body, including large areas of poison ivy, sunburn, or broken, blistered or oozing skin

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 right away

Directions

• adults and children 12 years of age and over: apply to affected area not more than 3

to 4 times daily

- children under 12 years of age: ask a doctor
- do not use more often than directed

Other information

• store at 59° to 77°F

Inactive ingredients

Cetyl alcohol, Glycerin, Glyceryl monostearate, levelling agent0, liquid paraffin, methylparaben, octadecyl alcohol, propyl 4-hydroxybenzoate, propylene glycol, purified water, stearic acid, vaseline

Package label

Anti-Itch Cream



Drug Facts

Active ingredients (in each gram)
Diphenhydramine HCl 2%..... PurposeTopical analgesic ..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

Drug Facts(continued)

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.

- 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: ask a doctor

Other information

■ protect from excessive heat (40°C/104°F)

Inactive ingredients cetearyl alcohol, glyceryl sterate, levelling agent 0, liquid parafin, methylparaben, octadecyl alcohol, propyl 4-hydroxybenzoate, propylene glycol, purified water, stearic acid, vaseline

Exclusively distributed by: Kareway Product Inc. 2550 S. Dominguez Hills Dr. Compton, CA 90220

Made in China

EXP.

LOT &



Relieves Itches from Insect Bites & Skin Irritations

CREAM ALLERGIC

Histamine Blocker

NET 1 oz(28.3g)

2% Diphenhydramine Hydrochloride

Relieves Itches from Insect Bites & Skin Irritations

ALLERGIC CREAM

Histamine Blocker

EXTRA STRENCTH





Compare to extra Strength Benadryl® active ingredients*

NDC No. 67510-0054-1
Pure-Aid TM



EXTRA STRENCTH

ANTI ITCH

diphenhydramine hcl, zinc acetate cream

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67510-0054		
Route of Administration	TOPICAL				

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ZINC ACETATE (UNII: FM5526K07A) (ZINC CATION - UNII:13S1S8SF37)	ZINC ACETATE	0.1 g in 100 g		
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	2 g in 100 g		

Inactive Ingredients		
Ingredient Name	Strength	
PARAFFIN (UNII: 1900E3H2ZE)		
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)		
CETYL ALCOHOL (UNII: 936JST6JCN)		
GLYCERIN (UNII: PDC6A3C0OX)		
METHYLPARABEN (UNII: A2I8C7HI9T)		
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
PROPYLPARABEN (UNII: Z8IX2SC10H)		
WATER (UNII: 059QF0KO0R)		

P	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:67510- 0054-2	1 in 1 BOX	08/11/2011				
1		57 g in 1 TUBE; Type 0: Not a Combination Product					
2	NDC:67510- 0054-1	1 in 1 BOX	08/11/2011				
2		28 g in 1 TUBE; Type 0: Not a Combination Product					

Marketing Information					
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
part348	08/11/2011				
	Application Number or Monograph Citation	Application Number or Monograph Marketing Start Citation Date			

Labeler - Kareway Product, Inc. (121840057)

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