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.

Soundbody Anti-itch Cream

Active ingredients (in each gram)

Diphenhydramine HCI 2%

Zinc acetate 0.1%

Purpose

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

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 right away.

Directions

- do not use more often 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

• store at 20° - 25°C (68° - 77°F)

Inactive ingredients

cetearyl alcohol, ethylparaben, glycerin, glyceryl stearate, mineral oil, polysorbate 80, propylene glycol, stearic acid, stearyl alcohol, water

Questions or Comments?

1-800-883-0085

Package label

Anti-Itch Cream



ANTI-ITCH

diphenhydramine hcl, zinc acetate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67510-0633
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	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)		
CETYL ALCOHOL (UNII: 936JST6JCN)		
GLYCERIN (UNII: PDC6A3C0OX)		
GLYCERYL 1-STEARATE (UNII: 258491E1RZ)		
MINERAL OIL (UNII: T5L8T28FGP)		
ETHYLPARABEN (UNII: 14255EXE39)		
POLYSORBATE 60 (UNII: CAL22UVI4M)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		

F	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:67510- 0633-2	1 in 1 BOX	12/13/2013			
1		56.6 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	12/13/2013		

Labeler - Kareway Product, Inc. (121840057)

Revised: 2/2023 Kareway Product, Inc.