ANTI ITCH CREAM - diphenhydramine hcl, zinc acetate cream
NeoPharm 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 (in each gram)

Diphenhydramine HCl 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

Carbomer 940, Cetyl alcohol, Glycerin, Glyceryl monostearate, Light liquid paraffin, Methylparaben, Myristoyl/palmitoyl oxostearamide/ arachamide MEA, PEG-15 glyceryl stearate, Stearic acid, Propylparaben, Purified water

Package label

Anti-Itch Cream

ANTI ITCH CREAM

diphenhydramine hcl, zinc acetate cream

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51141-0054
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 - UNII:J41CSQ7QDS)	ZINC ACETATE	0.1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PARAFFIN (UNII: I9O0E3H2ZE)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51141-0054-2	1 in 1 BOX		
1		57 g in 1 TUBE		
2	NDC:51141-0054-1	1 in 1 BOX		
2		28 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part336	09/07/2010	

Labeler - NeoPharm Co., Ltd. (631101883)

Registrant - NeoPharm Co., Ltd. (631101883)

Establishment

Name	Address	ID/FEI	Business Operations

NeoPharm Co., Ltd.		631101883	manufacture