DIPHENHYDRAMINE D- diphenhydramine hcl, zinc acetate cream
NexMed (USA), 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

Diphenhydramine hydrochloride 2%

Zinc acetate 0.1%

Purpose

Topical Analgesic

Skin protectant

Uses

- For the temporary relief of itching and pain 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.

Ask a doctor before use

- on chicken pox
- on measles

When using this product

- avoid contact with the eyes

Stop use and ask a doctor if

condition worsens or does not improve within 7 days, or symptoms persist for more than 7 days or clear up and occur again within a few days.

Do not use

- on large areas of the body

- with any other product containing diphenhydramine, even one taken by mouth

Keep out of reach of children.
If swallowed, get medical help or contact a Poison Control Center right away.

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, or as directed by a doctor
- **children under 2 years of age**, consult a doctor

Other information
- Store between 20º and 25ºC (68º to 77ºF)
- Lot no. and Exp. Date: see box or see crimp of tube
- Keep box for complete instructions and labeling

Inactive Ingredients

cetyl alcohol, diazolidinyl urea, dodecyl-2-N,N-dimethylaminopropionate hydrochloride, methylparaben, PEG-2 stearate, PEG-20 stearate, propylene glycol, propylparaben, purified water

Call 1-866-580-7391, Mon - Fri, 8:30 AM - 5:30 PM (PST)

DIPHENHYDRAMINE D

diphenhydramine hcl, zinc acetate cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:40002-004
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	.1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CETYL ALCOHOL (UNII: 936JST6JCN)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
Dodecyl-2-N,N-Dimethylaminopropionate Hydrochloride (UNII: 18F5YMF989)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PEG-2 STEARATE (UNII: 94YQ11Y95F)	
PEG-20 STEARATE (UNII: NBX892EA57)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:40002-004-03	1 in 1 CARTON		
1	NDC:40002-004-02	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	08/29/2011	

Labeler - NexMed (USA), Inc. (031710528)

Registrant - NexMed (USA), Inc. (031710528)

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