

DERMAMINE EXTRA STRENGTH ITCH STOPPING- diphenhydramine and zinc acetate cream

Natureplex 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.

**Dermamine
Extra Strength Itch Stopping Cream**

Drug Facts

<i>Active ingredients</i>	<i>Purposes</i>
Diphenhydramine Hydrochloride 2%	Topical Analgesic
Zinc Acetate 0.1%	Skin Protectant

Uses

- Temporarily relieves pain and itching associated with:
 - insect bites
 - minor burns
 - sunburn
 - scrapes
 - minor skin irritations
 - minor cuts
 - 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
- symptoms persist for more than 7 days or clear up and occur again within a few days

Keep out of the reach of children. In case of accidental ingestion, seek medical attention right away or contact a 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: ask a doctor

Other information

- store between 15° and 30° C (59° and 86° F)
- close cap tightly after use
- do not use if seal on tube is punctured or missing

Inactive ingredients

DMDM Hydantoin, GMS, isopropyl myristate, light mineral oil, methylparaben, propylparaben, ritacol, purified water

Questions or comments?

1-866-323-0107

PRINCIPAL DISPLAY PANEL - 35 g Tube Box

EXTRA STRENGTH

BLOCKS

**THE ITCH-CAUSING
HISTAMINES**

Natureplex™

Dermamine

Itch Stopping

Cream

Topical Analgesic Skin Protectant

NDC 67234-023-01

NET WT. 1.25 Oz.(35g)

diphenhydramine and zinc acetate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67234-023
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE (UNII: 8GTS82S83M) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE	0.02 mg in 1 g
ZINC ACETATE (UNII: FM5526K07A) (ZINC CATION - UNII:13S1S8SF37)	ZINC ACETATE	0.001 U in 1 g

Inactive Ingredients

Ingredient Name	Strength
DMDM HYDANTOIN (UNII: BYR0546TOW)	
GLYCERYL 1-STEARATE (UNII: 258491E1RZ)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67234-023-01	1 in 1 BOX	03/01/2014	
1		35 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 NOT FINAL	part348	03/01/2014	

Labeler - Natureplex LLC (062808196)

Establishment

Name	Address	ID/FEI	Business Operations
Natureplex LLC		062808196	MANUFACTURE(67234-023)