

ANTI-ITCH- zinc acetate , diphenhydramine cream
OL PHARMA TECH, 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.

Active Ingredients

Diphenhydramine hydrochloride 1%

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, 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

Do Not Use

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

When using this product

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 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

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

Inactive Ingredients

cetostearyl alcohol, sodium cetostearyl sulfate, stearic acid, trolamine, mineral oil, propylene glycol, water, methyl paraben, propyl paraben, EDTA, vitamin E

Questions

drspharmacyusa.com

Directions

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Itch stopping cream

ANTI-ITCH

zinc acetate , diphenhydramine cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80489-005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	1 g in 100 g
ZINC ACETATE (UNII: FM5526K07A) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	0.1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
DECYL OLEATE (UNII: ZGR06DO97T)	
TROLAMINE (UNII: 903K93S3TK)	

EDETATE DISODIUM (UNII: 7FLD91C86K)	
WATER (UNII: 059QF0KO0R)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
MINERAL OIL (UNII: T5L8T28FGP)	
SODIUM CETOSTEARYL SULFATE (UNII: 7ZBS06BH4B)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80489-005-01	1 in 1 CARTON	01/01/2021	
1		28.3 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	01/01/2021	

Labeler - OL PHARMA TECH, LLC (021170377)

Registrant - OL PHARMA TECH, LLC Drs PHARMACY (021170377)

Establishment

Name	Address	ID/FEI	Business Operations
OL PHARMA TECH, LLC Drs PHARMACY		021170377	manufacture(80489-005)

Revised: 10/2023

OL PHARMA TECH, LLC