OLP ANTI-ITCH ALLERGY RELIEF- diphenhydramine cream
OHIO LAB PHARMA 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%

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.

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 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

Other information

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

inactive ingredients

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

Questions

www.ohiolabpharma.us

Net weight 20 g

NDC#70648-133-01

OLP ANTI-ITCH ALLERGY RELIEF

diphenhydramine cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70648-133
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	10 mg in 1 g

ZINC ACETATE (UNII: FM5526K07A) (ZINC CATION - UNII:13S1S8SF37)	ZINC ACETATE	1 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
DECYL OLEATE (UNII: ZGR06DO97T)	
SODIUM CETOSTEARYL SULFATE (UNII: 7ZBS06BH4B)	
TROLAMINE (UNII: 9O3K93S3TK)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
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:70648-133-01	1 in 1 CARTON	02/21/2018	
1		20 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	02/21/2018	

Labeler - OHIO LAB PHARMA LLC. (080215854)

Establishment

Name	Address	ID/FEI	Business Operations
OHIO LAB PHARMA LLC.		080215854	manufacture(70648-133)

Revised: 11/2018 OHIO LAB PHARMA LLC.