DIPHENHYDRAMINE HCL AND ZINC ACETATE- diphenhydramine hydrochloride, zinc acetate cream

A-S Medication Solutions

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.

Perrigo Diphenhydramine HCI & Zinc Acetate Drug Facts

Active ingredients

Diphenhydramine hydrochloride 2%

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

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 the 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 no more than 3 to 4 times daily
- children under 2 years of age: ask a doctor

Other information

• store at 20°-25°C (68°-77°F)

Inactive ingredients

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

Questions or comments?

1-800-719-9260

DIPHENHYDRAMINE HCL AND ZINC ACETATE



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diphenhydramine hydrochloride, zinc acetate cream

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:50090-6465(NDC:45802-358)

Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
	DIPHENHYDRAMINE HYDROCHLORIDE	2 g in 100 g	
ZINC ACETATE (UNII: FM5526K07A) (ZINC CATION - UNII:13S1S8SF37)	ZINC ACETATE	0.1 g in 100 g	

Inactive Ingredients			
Ingredient Name	Strength		
CETYL ALCOHOL (UNII: 936JST6JCN)			
DIAZOLIDINYL UREA (UNII: H5RIZ 3MPW4)			
METHYLPARABEN (UNII: A218C7H19T)			
PEG-2 STEARATE (UNII: 94YQ11Y95F)			
PEG-20 STEARATE (UNII: NBX892EA57)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
PROPYLPARABEN (UNII: Z8IX2SC1OH)			
WATER (UNII: 059QF0KO0R)			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090- 6465-0	144 in 1 CASE	05/04/2023	
1		28 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	12/05/2005	

Labeler - A-S Medication Solutions (830016429)

Establishment			
Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-6465)

Revised: 5/2023 A-S Medication Solutions