

DIPHENHYDRAMINE - diphenhydramine hydrochloride, zinc acetate cream
Physicians Total Care, 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.

Active ingredient

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?

1-800-616-2471

Principal Display Panel

Diphenhydramine Hydrochloride 2%

Cream

28 g

NDC 54868-0113-0



Extra Strength

Anti-Itch Cream

Topical Analgesic/Skin Protectant

Additional barcode labeling by:

Physicians Total Care, Inc.

Tulsa, Oklahoma 74146

DIPHENHYDRAMINE

diphenhydramine hydrochloride, zinc acetate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54868-0113(NDC:0904-5354)
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	0.1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CETYL ALCOHOL (UNII: 936JST6JCN)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
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:54868-0113-0	1 in 1 CARTON		
1		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	04/23/2008	

Labeler - Physicians Total Care, Inc. (194123980)**Establishment**

Name	Address	ID/FEI	Business Operations
Physicians Total Care, Inc.		194123980	relabel