LEADER ANTI ITCH- diphenhydramine hydrochloride, zinc acetate cream Cardinal Health 110, LLC. dba Leader

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.

Cardinal Health Anti-Itch Cream 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

Principal Display Panel

LEADER™

Extra Strength Anti-Itch Cream

Diphenhydramine Hydrochloride, 2% | Zinc Acetate, 0.1%

Topical Analgesic | Skin Protectant

Itch Stopping Cream

COMPARE TO EXTRA STRENGTH BENADRYL® CREAM active ingredients

100% Money Back Guarantee

NET WT 1 OZ (28 g)



LEADER ANTI ITCH

diphenhydramine hydrochloride, zinc acetate cream

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0388	
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 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)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
PROPYLPARABEN (UNII: Z8IX2SC1OH)		
WATER (UNII: 059QF0KO0R)		
PEG-2 STEARATE (UNII: 94YQ11Y95F)		
PEG-20 STEARATE (UNII: NBX892EA57)		

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:70000- 0388-1	1 in 1 CARTON	12/13/2018			
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	12/13/2018		

Labeler - Cardinal Health 110, LLC. dba Leader (063997360)

Revised: 3/2022 Cardinal Health 110, LLC. dba Leader