LEADER ANTI ITCH MAXIMUM STRENGTH- diphenhydramine hydrochloride, zinc acetate cream
CARDINAL HEALTH

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.

Leader Anti-Itch Cream 1 oz. NBE Benadryl Maximum Strength

Active ingredients Purpose

Diphenhydramine Hydrochloride 2%.....Topical analgesic

Zinc acetate 0.1%.....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

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 between 20 ºC and 25 ºC (68 ºF and 77 ºF)

Inactive ingredients

cetyl alcohol, diazolidinyl urea, methylparaben, polyethylene glycol monostearate 1000, propylene glycol, propylparaben, and purified water

DISTRIBUTED BY CARDINAL HEALTH

DULIN, OHIO 43017

CIN 2372134

www.myleader.com

1-800-200-6313

Enter section text here

LEADER ANTI ITCH MAXIMUM STRENGTH

diphenhydramine hydrochloride, zinc acetate cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:37205-278
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: H5RIZ3MPW4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:37205-278-10	1 in 1 CARTON	02/10/2012	
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	02/10/2012	

Labeler - CARDINAL HEALTH (097537435)

Revised: 12/2017 CARDINAL HEALTH