ANTI-ITCH- diphenhydramine hydrochloride and zinc acetate cream
Universal Distribution Center 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.

Anti-Itch Cream

Active Ingredients

Diphenhydramine Hydrochloride 2%

Zinc Acetate 0.1%

Purpose

Topical Analgesic

Skin Protectant

Uses

For the temporary relief of pain and itching associated with:

- minor skin irritation
- allergic itches
- rashes
- hives
- minor burns
- insect bites
- poison ivy
- poison oak
- poison sumac

Warnings

Do not use on children under 2 years of age.

For external use only

- avoid contact with eyes
- do not apply to open wound or damaged skin.

Stop use and ask a doctor

- if condition worsens
- symptoms persist for 7 days or clear up and occur again within a few days.

Keep out of reach of children.

In case of accidental ingestion, get medical help or contact a Poison Control Center right away.

Directions

- For children 2 years of age and older: Apply to affected area not more than 3 to 4 times daily.

- For children under 2 years of age: consult a physician.

Other information

- Store at 20ºC to 25ºC (68ºF to 77ºF).

Inactive ingredients

Cetyl Alcohol, Diazolidinly urea, Methylparaben, Polyethylene Glycol Monostearate 1000, Propylene Gylcol, Propylparaben, Aloevera extract, Alpha-Tocopherol Acetate, Purified Water.

PRINCIPAL DISPLAY PANEL

Anti-Itch Cream

NET WT 1 OZ (28 g)

ANTI-ITCH

diphenhydramine hydrochloride and zinc acetate cream

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52000-023
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	0.02 g in 1 g
ZINC ACETATE (UNII: FM5526K07A) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	0.001 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
WATER (UNII: 059QF0KO0R)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PEG-20 STEARATE (UNII: NBX892EA57)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52000-023-37	1 in 1 BOX	02/14/2022	
1	NDC:52000-023-39	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	04/15/2015	

Labeler - Universal Distribution Center LLC (019180459)

Registrant - Anicare Pharmaceuticals Pvt. Ltd (916837425)

Establishment

Name	Address	ID/FEI	Business Operations
Anicare Pharmaceuticals Pvt. Ltd		916837425	manufacture(52000-023)