ANTI-ITCH CREAM- diphenhydramine hcl / zinc acetate cream
Front Pharmaceutical PLC

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.

Fourstar Group Anti-Itch Cream

Active Ingredients

Diphenhydramine hydrochloride 2%

Zinc Acetate 0.1%

Purpose

Topical Analgesic

Skin Protectant

Use

for temporary relief from pain and itching associated with insect bites, sunburn, and minor skin irritations. Dries the oozing and weeping of poison:

- ivy
- oak
- sumac

For external use only

Do not use

- over large areas of the body
- with any other product containing diphenhydramine, including those taken orally

When using this product

- avoid contact with eyes

Ask a doctor before use

- on chicken pox
- on measles

Stop use and ask a doctor if

- symptoms last for more than 7 days
- the condition gets worse

- symptoms clear up and then 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

- adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times per day.
- children under 2 years of age: ask a doctor before use

Inactive ingredients

cetyl alcohol, glyceryl monostearate, methylparaben, mineral oil, petrolatum, polyoxyethylene lauryl ether, propylene glycol, propylparaben, purified water, stearic acid, stearyl alcohol

Questions

1-800-639-3803 Weekdays 9 AM to 4 PM EST

Other information

- store at room temperature 59 degrees - 77 degrees F (15 degrees - 25 degrees C).
- tamper-evident: do not use if foil seal is broken or missing.

Extra Strength

Anti-Itch Cream

Topical Analgesic and Skin Protectant Cream

Net Wt 1 oz (28 g)

ANTI-ITCH CREAM

diphenhydramine hcl / zinc acetate cream

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69571-011
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 CATION	0.1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
MINERAL OIL (UNII: T5L8T28FGP)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
LAURETH-15 (UNII: 002FR4N8OV)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PETROLATUM (UNII: 4T6H12BN9U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69571-011-01	1 in 1 BOX	09/25/2023	
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	09/25/2023	

Labeler - Front Pharmaceutical PLC (530897792)

Establishment

Name	Address	ID/FEI	Business Operations
Front Pharmaceutical		530897792	manufacture(69571-011)