THE ITCH ERASER GEL- diphenhydramine hcl gel Adventure Ready Brands

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.

The Itch Eraser Gel

Active Ingredient

Diphenhydramine HCl 2%

Purpose

Topical Analgesic

Uses

For the temporary relief of pain and itching associated with

- insect bites
- minor burns
- sunburn
- minor skin irritations
- minor cuts
- rashes due to poison ivy, poison oak, and poison sumac

Warnings

For external use only

Do not use

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

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- on chicken pox
- on measles

When using

When using this product avoid contact with eyes.

Stop use and ask a doctor if

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

Keep out of reach of children

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Directions

- do not use more than directed
- adults and children over 2 years of age and older: apply to affected area not more than 3 to 4 times daily
- children under 2 years of age: ask a doctor

Inactive Ingredients

Aloe Vera, Citric Acid, Ethyl Alcohol, Glycerin, Methocel, Methylparaben, Oat Beta Glucan, Propylparaben, Purified Water, Sodium Hydroxide, Tea Tree Oil, Vitamin E

Package Labeling



THE ITCH ERASER GEL

diphenhydramine hcl gel

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:90107-2400

Route	of Administration	
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Active Ingredien	Active molety			
	Ingredient Name	Basis of St	trength	Strengt
DIPHENHYDRAMINE UNII:8GTS82S83M)	HYDRO CHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAM	INE - DIPHENHYDRAMI HYDROCHLORIDH		20 mg in 1 g
Inactive Ingredie	nts			
	Ingredient Name		S	trength
ALOE VERA LEAF (U	NII: ZY8 1Z8 3H0 X)			
ANHYDRO US CITRIC	ACID (UNII: XF417D3PSL)			
ALCOHOL (UNII: 3K9	958V90M)			
PROPYLPARABEN (U	NII: Z8IX2SC1OH)			
METHYLPARABEN (U	JNII: A218 C7H19 T)			
TEA TREE OIL (UNII:	VIF565UC2G)			
METHYLCELLULOS	E (100 CPS) (UNII: 4GFU244C4J)			
OATMEAL (UNII: 8 PIE	4V663Y)			
WATER (UNII: 059QF)KO0R)			
SO DIUM HYDRO XID	E (UNII: 55X04QC32I)			
ALPHATOCOPHER	OL ACETATE (UNII: 9E8X80D2L0)			
GLYCERIN (UNII: PDC	6A3C0OX)			
Packaging				
# Item Code	Package Description M	arketing Start Date	Marketin	ig End Date
1 NDC:90107-2400-1	1 in 1 BOX 09	/01/2020		

1 NDC:90107-2400-1	1 in 1 BOX	09/01/2020
1	57 g in 1 TUBE; Type 0: Not a Combination Product	
2 NDC:90107-2400-0	57 g in 1 TUBE; Type 0: Not a Combination Product	09/01/2020

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	09/01/2020		

Labeler - Adventure Ready Brands (064437304)

Registrant - Adventure Ready Brands (064437304)

Establishment					
Name	Address	ID/FEI	Business Operations		
Adventure Ready Brands		064437304	manufacture(90107-2400)		