AFTER BITE XTRA- 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.

After Bite Xtra

Active Ingredient

Diphenhydramine HCl 2%

Purpose

Topical Analgesic

Uses

For the temporary relief of pain and itching associated with

- minor burns
- minor cuts
- scrapes
- insect bites
- minor skin irritations
- 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

AFTER BITE XTRA

diphenhydramine hcl gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:90107-1270
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	20 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ALCOHOL (UNII: 3K9958V90M)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
TEA TREE OIL (UNII: VIF565UC2G)	
METHYLCELLULOSE (100 CPS) (UNII: 4GFU244C4J)	
OATMEAL (UNII: 8PI54V663Y)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:90107-1270-1	1 in 1 BOX	09/01/2020	
1		20 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:90107-1270-0	20 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(90107-1270)

Revised: 9/2020 Adventure Ready Brands