EXTRA STRENGTH FIRST AID ANTI-ITCH RITE AID PHARMACY- diphenhydramine hcl 2% gel

Rite Aid

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.

Drug Facts

Active ingredient Purpose

Diphenhydramine HCI 2%.....Topical analgesic

Uses Temporarily relieves pain due to: • minor burns • insect bites • sunburn • minor skin irritations • minor cuts • scrapes • rashes due to poison ivy, poison oak & 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

When using this product • avoid contact with the eyes

Stop use and ask doctor if • condition gets worse • symptoms last more than 7 days • symptoms clear up and occur again in a few days.

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

Directions • do not use more than directed • adults and children 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

Camphor, Citric Acid, Diazolidinyl Urea, Glycerin, Hydroxypropyl Methylcellulose, Methylparaben, Propylene Glycol, Propylparaben, SD Alcohol 38-B, Sodium Citrate, Water.





EXTRA STRENGTH FIRST AID ANTI-ITCH RITE AID PHARMACY

diphenhydramine hcl 2% gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:11822-7797

Route of Administration TOPICAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength DIPHENHYDRAMINE HYDRO CHLO RIDE (UNII: TC2D6 JAD40) (DIPHENHYDRAMINE - UNII:8 GTS82S83M) DIPHENHYDRAMINE HYDRO CHLO RIDE (UNII: TC2D6 JAD40) (DIPHENHYDRAMINE - HYDRO CHLO RIDE in 100 mL

Inactive Ingredients				
Ingredient Name	Strength			
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)				
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)				
Diazolidinyl Urea (UNII: H5RIZ3MPW4)				
Glycerin (UNII: PDC6A3C0OX)				
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)				
Methylparaben (UNII: A2I8C7HI9T)				
Propylene Glycol (UNII: 6DC9Q167V3)				
Propylparaben (UNII: Z8IX2SC1OH)				

ALCOHOL (UNII: 3K9958V90M)	
Sodium Citrate (UNII: 1Q73Q2JULR)	
Water (UNII: 059QF0KO0R)	

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:11822-7797-4	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	0 1/30 /20 13		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	0 1/30/20 13		

Labeler - Rite Aid (014578892)

Registrant - Product Quest Mfg (927768135)

Establishment				
Name	Address	ID/FEI	Business Operations	
Product Quest Mfg		927768135	manufacture(11822-7797), label(11822-7797)	

Revised: 1/2017 Rite Aid