ITCH RELIF CVS- diphenhydramine hydrochloride gel
CVS

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 HCl 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

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.

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

Ask a doctor before use • on chicken pox • on measles

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.

Inactive ingredients:

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

ITCH RELIF CVS

diphenhydramine hydrochloride gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69842-038
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 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ALCOHOL (UNII: 3K9958V90M)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
Diazolidinyl Urea (UNII: H5RIZ3MPW4)	
Glycerin (UNII: PDC6A3C0OX)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
Methylparaben (UNII: A2I8C7HI9T)	
Propylene Glycol (UNII: 6DC9Q167V3)	

Propylparaben (UNII: Z8IX2SC1OH)	
Water (UNII: 059QF0KO0R)	
Sodium Citrate (UNII: 1Q73Q2JULR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-038-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/14/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	02/14/2014	

Labeler - CVS (062312574)

Registrant - Product Quest Mfg (927768135)

Establishment

Name	Address	ID/FEI	Business Operations
Product Quest Mfg		927768135	manufacture(69842-038) , label(69842-038)

Revised: 12/2017 CVS