CVS MAXIMUM STRENGTH ITCH RELIEF- diphenhydramine hydrochloride gel
CVS Pharmacy

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

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

Uses

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- minor burns - insect bites - sunburn - minor skin irritations
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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 a doctor if condition worsens, or if the symptoms persist for more than 7 days or clear up and 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

- do not use more than directed

- **Adults and children 2 years and older:** apply to affected area not more than 3 to 4 times daily

- **Children under 2 years of age:** ask a doctor

Other information

Store at 20 degrees to 25 degrees C (68 degrees to 77 degrees F)

Inactive Ingredients

purified water, SD alcohol 40-B, propylene glycol, diazolidinyl urea, hydroxypropyl methylcellolose, camphor, methylparaben, citric acid, sodium citrate, propylparaben

CVS MAXIMUM STRENGTH ITCH RELIEF

diphenhydramine hydrochloride gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59779-048

Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	20.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
HYPROMELLOSE 2910 (4000 MPA.S) (UNII: RN3152OP35)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-048-69	118 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part336	08/10/2011	

Labeler - CVS Pharmacy (062312574)

Registrant - Pharma Pac, LLC (140807475)

Establishment

Name	Address	ID/FEI	Business Operations
Pharma Pac, LLC		140807475	manufacture

Revised: 4/2012 CVS Pharmacy