

RITE AID MAXIMUM STRENGTH ITCH RELIEF- diphenhydramine hydrochloride gel
RITE AID CORPORATION

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.

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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 methylcellulose, camphor, methylparaben, citric acid, sodium citrate, propylparaben



Drug Facts	
DO NOT USE IF SEAL UNDER CAP IS TORN OR MISSING	
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Diphenhydramine HCl 2%	Topical analgesic
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When using this product avoid contact with the eyes	
Stop use and ask a doctor if condition worsens, or if 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 of age & older: apply to the affected area not more than 3 to 4 times daily ■ Children under 2 years of age: ask a doctor	
Other information store at 20° to 25°C (68° to 77°F)	
Inactive ingredients purified water, SD alcohol 40-B, propylene glycol, diazolidinyl urea, hydroxypropyl methylcellulose, camphor, methylparaben, citric acid, sodium citrate, propylparaben	
*This product is not manufactured or distributed by McNeil-PPC, Inc., owner of the registered trademark Benadryl®. R249RAD40Z-1	
IF YOU'RE NOT SATISFIED, WE'LL HAPPILY REFUND YOUR MONEY.	
DISTRIBUTED BY: RITE AID 30 HUNTER LANE CAMP HILL, PA 17011	 0 11822 92813 7
Non-Varnish Area	

diphenhydramine hydrochloride gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-0370
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: 059QF0K00R)	
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:11822-0370-2	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 - RITE AID CORPORATION (014578892)

Registrant - Pharma Pac, LLC (140807475)

Establishment

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

