ITCH RELIEF- diphenhydramine hydrochloride spray
Water-Jel Technologies, LLC.

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.

Itch Relief

Active ingredient

Diphenhydramine hydrochloride 2%

Purpose

External analgesic

Uses

for temporary relief of pain and itching associated with minor bums, minor cuts, scrapes, insect bites or minor skin irritations

For external use only

Do not use

• on large areas of the body

• on broken, blistered or oozing skin • on poison ivy or sunburn
• more often than directed
• wtth any other product containing diphenhydramlne, even one taken by mouth
• on chicken pox or measles

When using this product

avoid contact with the eyes

Stop use and ask a doctor if

• condition worsens • symptoms persist for more than 7 days • condition clears up and occurs again within few days

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

• adults and children 2 years of age and older:

apply to affected area not more than 3-4 times daily

• children under 2 years: consult a doctor

Other Information

• store at room temperature
• you may report a serious adverse reaction to this product to 1-800-275-3433

Inactive ingredients

diazolidinyl urea, edetate disodium, glycerin, hypromellose, methylparaben, octoxynol 9, propylene glycol, propylparaben, trolamine, water

Questions or comments?

1-800-275-3433 info@waterjel.com www.waterjel.com

Manufactured by Water-Jel Technologies Inc.

50 Broad Street, Carlstadt, NJ 07072

Principal Display Panel

ITCH RELIEF

diphenhydramine hydrochloride spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59898-810
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
EDETATE DISODIUM (UNII: 7FLD91C86K)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
OCTOXYNOL 9 (UNII: 7JPC6Y25QS)	
TROLAMINE (UNII: 9O3K93S3TK)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59898-810-10	59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	09/25/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/25/2010	

Labeler - Water-Jel Technologies, LLC. (155522589)

Registrant - Water-Jel Technologies, LLC. (155522589)

Establishment

Name	Address	ID/FEI	Business Operations
Water-Jel Technologies, LLC.		155522589	manufacture(59898-810)

Revised: 12/2020 Water-Jel Technologies, LLC.