

EFFECTIVE ITCH RELIEF- diphenhydramine hci, zinc acetate spray

TopCo

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 ingredients

Diphenhydramine HCl 2.0%

Zinc Acetate 0.10%

Purpose

Topical analgesic

Skin protectant

Uses

Temporarily relieves pain and itching associated with:

- insect bites
- minor burns
- sunburn
- minor cuts
- scrapes
- minor skin irritations
- rashes due to poison ivy, oak and sumac
- dries the oozing and weeping of poison ivy, oak and sumac

Warnings

For external use only.

Flammable - Do not use while smoking or near heat or flame ☐☐☐☐

Do not use

- on large areas of the body
- with any other product containing diphenhydramine, even one taken by mouth
- on chicken pox

Stop use and ask a doctor if

- condition worsens
- symptoms last more than 7 days
- symptoms clear up and occur again in a few days

When using this product

keep out of eyes

use only as directed.

do not puncture or incinerate. Contents under pressure. Do not store at temperatures above 120F

Keep out of reach of children.

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

Directions

- shake well
- 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
- to apply to face, spray into palm of hand and gently apply

Inactive ingredients

Alcohol Denat.
Glycerin
PVP
Tromethamine
Water

TopCare®

Effective Itch Relief Spray

MAXIMUM STRENGTH

DIPHENHYDRAMINE HCL 2.00%
Topical Analgesic
ZINC ACETATE 0.10%
Skin Protectant

Continuous Spray
Histamine Blocking
Relieves Pain And Itch Associated With:

- Poison Ivy
- Oak Or Sumac Rash
- Insect Bites

Compare to Benadryl® active ingredients*

NET WT 3 OZ (85 g)

Drug Facts						
<table><thead><tr><th>Active ingredients</th><th>Purpose</th></tr></thead><tbody><tr><td>Diphenhydramine HCl 2.00%.....</td><td>Topical analgesic</td></tr><tr><td>Zinc Acetate 0.10%.....</td><td>Skin protectant</td></tr></tbody></table>	Active ingredients	Purpose	Diphenhydramine HCl 2.00%.....	Topical analgesic	Zinc Acetate 0.10%.....	Skin protectant
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Warnings For external use only. Flammable: Do not use while smoking or near heat or flame Do not use • on large areas of the body • with any other product containing diphenhydramine, even one taken by mouth • on chicken pox When using this product • keep out of eyes • use only as directed. • do not puncture or incinerate. Contents under pressure. Do not store at temperatures above 120°F. Stop use and ask doctor if • condition worsens • 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 immediately.						
Directions • shake well • 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 • to apply to face, spray into palm of hand and gently apply						
Inactive ingredients Alcohol Denat., Glycerin, PVP, Tromethamine, Water.						

*This product is not manufactured or distributed by Johnson & Johnson Consumer Products Company, owner and distributor of the Benadryl® trademark

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TOPCO ASSOCIATES LLC
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QUESTIONS? 1-888-423-0139
topcare@topco.com



This TOP CARE® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.



EFFECTIVE ITCH RELIEF

diphenhydramine hci, zinc acetate spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-739
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	2.0 g in 100 g
ZINC ACETATE (UNII: FM5526K07A) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	.10 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
GLYCERIN (UNII: PDC6A3C0OX)	
POVIDONE (UNII: FZ989GH94E)	
WATER (UNII: 059QF0K00R)	
TROMETHAMINE (UNII: 023C2WHX2V)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-739-03	85 g in 1 CAN; Type 0: Not a Combination Product	01/22/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/22/2013	

Labeler - TopCo (006935977)

Registrant - Product Quest Mfg, LLC (927768135)

Establishment

Name	Address	ID/FEI	Business Operations
Product Quest Mfg, LLC		927768135	manufacture(36800-739) , label(36800-739)