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

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: 059QF0KO0R)	
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)

Revised: 7/2018 TopCo