# ITCH RELIEF- diphenhydramine hci, zinc acetate spray Care One

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.

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## **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 [100]

#### Do not use

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

#### 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

**Other information** Store at 20° to 25°C (68° to 77°F)

Questions? 1-877-846-9949



### **ITCH RELIEF**

diphenhydramine hci, zinc acetate spray

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-350	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>DIPHENHYDRAMINE HYDRO CHLO RIDE</b> (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)	
PO VIDO NE (UNII: FZ989 GH94E)	
WATER (UNII: 059QF0KO0R)	
TROMETHAMINE (UNII: 023C2WHX2V)	

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-350-03	85 g in 1 CAN; Type 0: Not a Combination Product	02/24/2015	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	02/24/2015		

# **Labeler -** Care One (809183973)

# **Registrant -** Product Quest Mfg, LLC (927768135)

Establishment				
Name	Address	ID/FEI	Business Operations	
Product Quest Mfg, LLC		927768135	manufacture(41520-350), label(41520-350)	

Revised: 8/2018 Care One