QUALITY CHOICE ITCH RELIEF- diphenhydramine hcl, zinc acetate spray Chain Drug Marketing Association

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.

Quality Choice Extra Strength Itch Relief Spray

Active Ingredient

Diphenhydramine hydrochloride 2% Topical analgesic

Zinc acetate 0.1% Skin protectant

Uses

for

temporary relieves pain and itching due to:

insect bites

minor burns

sunburn

minor skin irritations

minor cuts

scrapes

rashes due to poison ivy, poison oak, and poison sumac

dries the oozing and weeping of poison:

ivy

oak

sumac

Directions

do not use more often 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: ask a doctor

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 doctor Before use

on chicken pox on measles

When using this product

do not get into eyes

Stop Use and ask physician

condition worsens

symptoms last 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.

Warning

for external use only

Purposes

Itch relief

Inactive Ingredients

Purified Water, Glycerin, SD Alcohol, Povidone, Povidonee (K-30), Trolamine

Prinicpal dispaly panel



Quality Choice

Compare to the active ingredients in BENADRYL® ITCH RELIEF SPRAY

Extra Strength Itch Relief Spray

Skin protectant Topical analgesic

Diphenhydramine hydrochloride 2% Zinc acetate 0.1%

For Skin Use Only

QUALITY CHOICE ITCH RELIEF

diphenhydramine hcl, zinc acetate spray

Product Type HUMAN OTC DRUG Item Code (Source) NDC:63868-952

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC ACETATE (UNII: FM5526K07A) (ZINC CATION - UNII:13S1S8SF37)	ZINC ACETATE	0.1 g in 100 mL
DIPHENHYDRAMINE HYDRO CHLO RIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	2 g in 100 mL

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
GLYCERIN (UNII: PDC6A3C0OX)		
ALCOHOL (UNII: 3K9958V90M)		
PO VIDONE K30 (UNII: U725QWY32X)		
TROLAMINE (UNII: 9O3K93S3TK)		

ı	Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1 NDC:63868-952- 02	59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/14/2014		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	0 4/14/20 14		

Labeler - Chain Drug Marketing Association (011920774)

Registrant - Weeks & LEO, Inc. (005290028)

Establishment			
Name	Address	ID/FEI	Business Operations
Weeks & Leo		005290028	manufacture(63868-952)

Revised: 4/2019 Chain Drug Marketing Association