ITCH STOPPING- diphenhydramine hcl gel
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 Stopping Gel

Active Ingredients

Diphenhydramine hydrochloride 2%..... Topical analgesic

Uses

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

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 chiken Pox

On Measles

When Using This Product

do not get into eyes

Stop Use and ask Doctor if

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.

Purpose

Anti itch

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

Other

store at 20 °C to 25 °C (68 °F to 77 °F)

Inactive Ingredients

camphor, citric acid, diazolidinyl urea, hypromellose, methylparaben, propylene glycol, propylparaben, purified water,
SD alcohol 40-B, sodium citrate

dosage and administration

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

Principal Dipslay label

Quality Choice QC

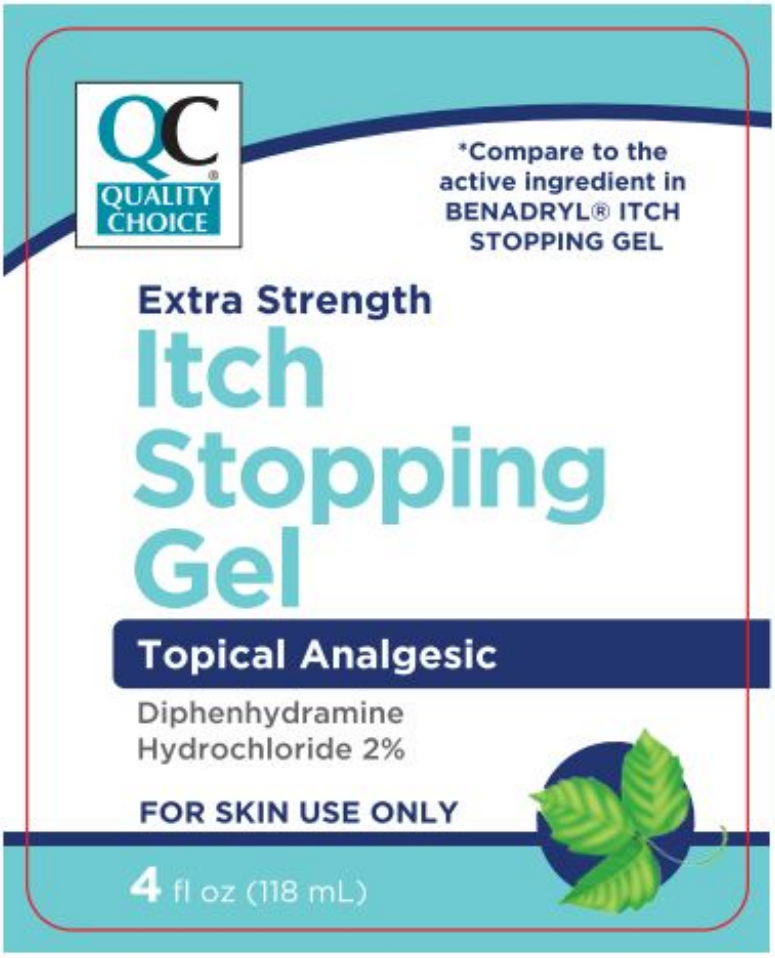
Compare to the active ingredient in Benadryl Gel

Extra strength Itch Relief Gel

Topical Analgesic

Diphenhydramine HCL 2%

For skin use only



ITCH STOPPING

diphenhydramine hcl gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63868-260
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 g

Inactive Ingredients	
Ingredient Name	**Strength**
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
ALCOHOL (UNII: 3K9958V90M)	
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
HYPROMELLOSE 2910 (4000 MPA.S) (UNII: RN3152OP35)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-260-04	113 g in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/14/2014	

Labeler - Chain Drug Marketing Association (011920774)

Registrant - Weeks & Leo (005290028)

Establishment

Name	Address	ID/FEI	Business Operations
weeks and Leo		005290028	manufacture(63868-260)

Revised: 11/2020 Chain Drug Marketing Association