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)

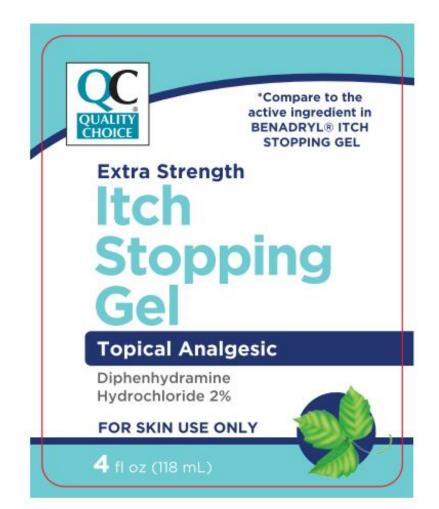
Inactive Ingredients

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		NDC:63868-2	2:63868-260	
Route of Administration	TOPICAL					
Active Ingredient/Active Mo	iety					
Ing	Basis of Strength Strength		Strengtl			
DIPHENHYDRAMINE HYDRO CHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - DIPHENHYDRAMINE - UNII:8GTS82S83M) DIPHENHYDRO CHLORIDE					2 g in 100 g	
Inactive Ingredients						
Ingredient Name					rength	
DIAZOLIDINYL UREA (UNII: H5RIZ3	MPW4)					
METHYLPARABEN (UNII: A2I8C7HI9						
TRISO DIUM CITRATE DIHYDRATE	(UNII: B22547B95K)					
ALCOHOL (UNII: 3K9958V90M)						
WATER (UNII: 059QF0KO0R)						
PROPYLENE GLYCOL (UNII: 6 DC90	(167V3)					

HVD	DOMELLOSE 2010	(A000 MDA S) (UNII) PN3152() D25)					
HYPROMELLOSE 2910 (4000 MPA.S) (UNII: RN3152OP35)							
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)							
PROPYLPARABEN (UNII: Z8IX2SC1OH)							
Packaging							
#	Item Code	Package Description	Marketing Start Date	Marketing End Dat			
1 NI	DC:63868-260-04 11	3 g in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2014				
Ma	rketing Infor	mation					
Ma	rketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Dat			
	monograph not final	part348	05/14/2014				
отс		1					

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: 5/2019

Chain Drug Marketing Association