

ITCH RELIEF GEL- itch relief gel gel
Humco Holding Group, Inc

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.

Private Label Itch Relief Gel

Do not use more often than directed.

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.

For external use only.

Camphor, Citric Acid, Diazolidnyl Urea, Glycerin, Hydroxypropyl Methylcellulose, Methylparaben, Propylene Glycol, Propylparaben, SD Alcohol 38-B, Sodium Citrate, Purified Water.

Temporarily relieves pain due to: Minor burns, insect bites, sunburn, minor skin irritation, minor cuts, scrapes, rashes due to poison ivy, poison oak and poison sumac.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

External Analgesic

Diphenhydramine HCl 2%

Equate Label



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<p>ITCH RELIEF GEL itch relief gel gel</p>
<p>Product Information</p>

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0395-9134
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	2 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
ALCOHOL (UNII: 3K9958V90M)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0395-9134-94	118 mL in 1 CONTAINER; Type 0: Not a Combination Product	12/20/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	12/20/2018	

Labeler - Humco Holding Group, Inc (825672884)

Registrant - Humco Holding Group, Inc (825672884)

Establishment

Name	Address	ID/FEI	Business Operations
Humco Holding Group, Inc		825672884	manufacture(0395-9134) , label(0395-9134) , pack(0395-9134) , analysis(0395-9134)