

## 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.

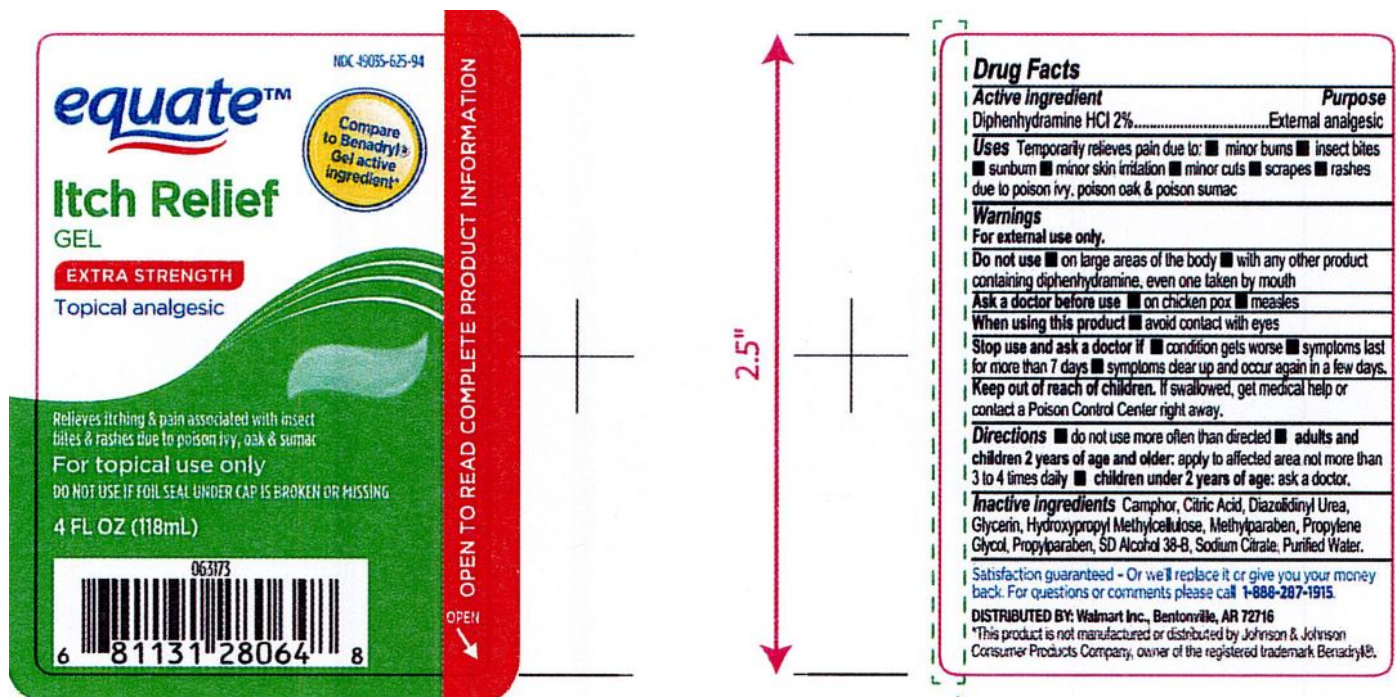
Temporarily relieves pain due to: Minor burns, insect bites, sunburn, minor skin irritation, minor cuts, scrapes, rashes due to poison ivy, poison oak and poison sumac.

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



## ITCH RELIEF GEL

itch relief gel gel

### Product Information

|  |                  |  |                             |                           |
|--|------------------|--|-----------------------------|---------------------------|
| <b>Product Type</b>  | HUMAN OTC DRUG   | <b>Item Code (Source)</b>                                | NDC:0395-9134               |                           |
| <b>Route of Administration</b>   | TOPICAL          |  |                             |                           |
|  |                  |  |                             |                           |
| <b>Active Ingredient/Active Moiety</b>   |                  |  |                             |                           |
| <b>Ingredient Name</b>   |                  | <b>Basis of Strength</b>                                 | <b>Strength</b>             |                           |
| DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M) |                  | DIPHENHYDRAMINE HYDROCHLORIDE                            | 2 mg<br>in 100 mL           |                           |
|  |                  |  |                             |                           |
| <b>Inactive Ingredients</b>  |                  |  |                             |                           |
| <b>Ingredient Name</b>   |                  |  | <b>Strength</b>             |                           |
| 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: 059QF0KO0R)   |                  |  |                             |                           |
| GLYCERIN (UNII: PDC6A3C0OX)  |                  |  |                             |                           |
|  |                  |  |                             |                           |
| <b>Packaging</b>   |                  |  |                             |                           |
| <b>#</b>   | <b>Item Code</b> | <b>Package Description</b>                               | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
| 1  | NDC:0395-9134-94 | 118 mL in 1 CONTAINER; Type 0: Not a Combination Product | 12/20/2018                  |                           |
|  |                  |  |                             |                           |
| <b>Marketing Information</b>   |                  |  |                             |                           |
| <b>Marketing Category</b>  |                  | <b>Application Number or Monograph Citation</b>          | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
| 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) |