HUMCO CALAMINE- calamine 8% and zinc oxide 8% lotion 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.

Humco Calamine Lotion

Drug Facts

Active Ingredients

Calamine 8% and Zinc Oxide 8%

Purpose

Skin protectant

Uses

dries the oozing and weeping o poison ivy, poison oak, and poison sumac.

Warnings

For external use only. Use only as directed.

Avoid contact with eyes and mucous membranes.

Ask a doctor before using on chilren 6 months of age.

When using this product

Discontinue use if condition worsens or does not improve within 7 days and consult a doctor.

Keep out of reach of children

In case of accidental ingestion, seek professional assistance or contact a Poison Control center immediately.

Directions

Adults and chidren 2 years of age and older: shake well before using. Cleanse the skin with soap and water and let it dry befroe each use. Apply lotion to the affected area using a cotton or soft cloth, as often as needed for comfort.

Children under 6 months of age: Consult a doctor before use.

Other information

Store at room temperature 13-30C (50-86F)

Inactive ingredients

Bentonite magma, calcium hydroxide, glycerin, purified water.

Package Principal Display Panel



HUMCO CALAMINE

calamine 8% and zinc oxide 8% lotion

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0395-0413	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	160 mg in 1 mL		

Inactive Ingredients			
Ingredient Name	Strength		
BENTONITE (UNII: A3N5ZCN45C)			
CARRAGEENAN (UNII: 5C69 YCD2YJ)			
XANTHAN GUM (UNII: TTV12P4NEE)			
CALCIUM HYDRO XIDE (UNII: PF5DZW74VN)			
GLYCERIN (UNII: PDC6A3C0OX)			
WATER (UNII: 059QF0KO0R)			
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1 N		177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/13/20 17	
Marketing Information				
Ma	rketing Categor	ry Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ОТС	monograph final	part347	03/25/1998	

Labeler - Humco holding Group, Inc. (825672884)

Registrant - Humco holding Group, Inc. (825672884)

Establishment			
Name	Address	ID/FEI	Business Operations
Humco Holding Group, Inc.		825672884	label(0395-0413), manufacture(0395-0413), analysis(0395-0413), pack(0395-0413)

Revised: 12/2018 Humco holding Group, Inc.