CALAMINE PHENOLATED TOPICAL SUSPENSION- calamine and zinc oxide and phenol lotion
Humco Holding Group, Inc

Calamine PhenolatedTopical Suspension USP

Drug Facts

Active Ingredient

Calamine 8%

Purpose

Skin Protectant

Active Ingredient

Zinc Oxide 8%

Purpose

Skin Protectant

Active Ingredient

Liquefied Phenol 1%

Purpose

Topical Analgesic

Uses

Dries the oozing and weeping and temporarily pain and itching of poison ivy, poison oak, and poison sumac, or other minor skin irritations

Warnings

- **For external use only**. Use only as directed.
- **Avoid contact with** eyes and mucous membranes.
- **Do not apply to** large areas of the body or in large quantities, particularly over raw or blistered areas.
- **If applied to** fingers or toes do not bandage.

Ask a doctor

before using on children under 2 years of age.

When using this product. Discontinue use if condition worsen 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 (Shake well before using)

Adult and children 2 years of age and older: Cleanse the skin with soap and water and let dry before each use. Apply product to the affected area using cotton or soft cloth, as often as needed for comfort.

Children under 2 years of age: Consult a doctor before use.

Other Information.

Store at room temperature 15-30C (59-86F)

Inactive Ingredients.

Bentonite Magma, Calcium Hydroxide, Glycerin, Purified Water.

Principal Display Panel

CALAMINE PHENOLATED TOPICAL SUSPENSION

calamine and zinc oxide and phenol lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0395-0407
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
PHENOL (UNII: 339NCG44TV) (PHENOL - UNII:339NCG44TV)	PHENOL	10 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
BENTONITE (UNII: A3N5ZCN45C)	
CALCIUM HYDROXIDE (UNII: PF5DZW74VN)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0395-0407-96	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/13/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M016	03/25/1998	

Labeler - Humco Holding Group, Inc (825672884)

Registrant - Pharma Nobis, LLC (118564114)

Establishment

Name	Address	ID/FEI	Business Operations
Pharma Nobis, LLC		118564114	manufacture(0395-0407) , pack(0395-0407) , analysis(0395-0407) , label(0395-0407)

Revised: 12/2023 Humco Holding Group, Inc