

CALAMINE- calamine 8% and zinc oxide 8% lotion
Pierson Laboratories

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.

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 children 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 children 2 years of age and older: shake well before using. Cleanse the skin with soap and water and let it dry before 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.

Label

NDC 45591-041-96

CALAMINE LOTION

(Calamine Topical Suspension USP)

SKIN PROTECTANT



0 45591 04196 4
R030717DL

Drug Facts

Active ingredients	Purpose
Calamine 8%, Zinc Oxide 8%.....	Skin protectant
Uses	
Dries the oozing and weeping of poison ivy, poison oak, poison sumac.	
Warnings	
■ For External use only. Use only as directed.	
When using this product ■ Do not get in eyes.	
Stop use and ask a doctor if	
■ condition worsens ■ symptoms last for more than 7 days, or clear up and occur again within a few days.	
Keep out of reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.	
Directions	
■ Adults and children 2 years of age and older: Shake well before using. Cleanse the skin with soap and water and let dry before each use. Apply lotion to the affected area using cotton or soft cloth, as often as needed for comfort.	
■ Children under 6 months age: Consult a doctor before use.	
Other information ■ Store at room temperature 15-30°C	
Inactive ingredients Avical, Bentonite Magma, Calcium Hydroxide, Carrageenan, Glycerin, Purified Water, and Xanthan Gum.	

CONTENTS 6 FL OZ (177 mL)

Distributed by: Pierson Laboratories, PO Box 157, Saluda, NC 28773
 Questions or Comments? ☎1-800-662-3435

CALAMINE

calamine 8% and zinc oxide 8% lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:45591-041
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: 5C69YCD2YJ)	
XANTHAN GUM (UNII: TTV12P4NEE)	

CALCIUM HYDRO XIDE (UNII: PF5DZW74VN)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45591-041-96	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/14/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	12/14/2017	

Labeler - Pierson Laboratories (119184992)

Registrant - Humco Holding Group, Inc. (825672884)

Establishment

Name	Address	ID/FEI	Business Operations
Humco Holding Group, Inc.		825672884	label(45591-041) , manufacture(45591-041) , analysis(45591-041) , pack(45591-041)

Revised: 12/2017

Pierson Laboratories