CALAMINE- calamine and zinc oxide lotion Wal-mart Stores, 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.

Equate Calamine Lotion

CALAMINE- calamine 8% and zinc oxide 8% lotion Wal-Mart Stores, Inc.

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Equate Calamine Lotion

Drug Facts

Active Ingredients

Calamine 8% and Zinc Oxide 8%

Purpose

Skin protectant

Uses

dries the oozing and weeping of 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 under 2 years 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 15°-30°C (59°-86°F)

Inactive ingredients

Avicel, Bentonite magma, Calcium Hydroxide, Carrageenan, Glycerin, Purified Water, and Xanthan Gum.

Label

PRINCIPAL DISPLAY PANEL

NDC 49035-413-96 equate Calamine LOTION (Calamine topical suspension, USP) 6 FL OZ (177mL)



Revised: 12/2017 Wal-Mart Stores, Inc.

CALAMINE calamine and zinc oxide lotion Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:49035-413 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: PDC6 A3C0 OX)		
WATER (UNII: 059QF0KO0R)		
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)		

Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:49035-413- 96	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/30/2017	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part347	12/30/2017		

Labeler - Wal-mart Stores, Inc. (051957769)

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