

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

Equate 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 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.

label

Drug Facts

Active ingredients	Purpose
Calamine 8%, Zinc Oxide 8%.....	Skin protectant

Uses Dries the oozing and weeping of
poison ■ ivy ■ oak ■ sumac

Warnings
■ For external use only

When using this product ■ do not get
into eyes

Stop use and ask a doctor if
■ condition worsens ■ symptoms last
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 (1-800-222-1222) right away.

Continued

NDC 49035-475-96

equate™

Calamine
LOTION

(Calamine topical
suspension, USP)

• Skin protectant
• Poison Ivy, Oak and
Sumac drying lotion

6 FL OZ (177mL)







R040721

Drug Facts (continued)

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, no more than 3 to 4 times daily.
■ Children under 2 years of age: Consult a doctor before use.

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

Inactive ingredients
Bentonite Magma, Calcium Hydroxide, Carageenan, Glycerin,
Microcrystalline Cellulose, Purified Water, and Xanthan Gum.

DISTRIBUTED BY: Walmart Inc.,
Bentonville, AR 72716

Satisfaction guaranteed - For questions or
comments please call 1-888-287-1915.

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6 81131 17600 2

Drug Facts

Active ingredients	Purpose
Calamine 8%, Zinc Oxide 8%.....	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, does not improve or if
symptoms persist for more than 7 days, or
clear up and occur again within a few 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.

Continued

NDC 49035-475-96

equate™

Calamine
LOTION

(Calamine topical
suspension, USP)

• Skin Protectant
• Poison Ivy, Oak and
Sumac drying lotion

6 FL OZ (177mL)







R083017-RLG

Drug Facts (continued)

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 2 years 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.

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Bentonville, AR 72716

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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
CARRAGEENAN (UNII: 5C69YCD2YJ)				
BENTONITE (UNII: A3N5ZCN45C)				
XANTHAN GUM (UNII: TTV12P4NEE)				
CALCIUM HYDROXIDE (UNII: PF5DZW74VN)				
GLYCERIN (UNII: PDC6A3C0OX)				
WATER (UNII: 059QF0KO0R)				
MICROCRYSTALLINE CELLULOSE (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 Drug		M016	12/30/2017	

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

Registrant - Pharma Nobis, LLC (118564114)

Establishment			
Name	Address	ID/FEI	Business Operations
Pharma Nobis, LLC		118564114	label(49035-413) , manufacture(49035-413) , analysis(49035-413) , pack(49035-413)