

TOPCARE CALAMINE- calamine 8% and zinc oxide 8% lotion lotion
TOPCO ASSOCIATES LLC

Top Care Calamine Lotion

Calamine 8% and Zinc Oxide 8%

Skin protectant

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

For external use only. Use only as directed.

Avoid contact with eyes and mucous membranes.

Ask a doctor before using on children 2 years of age.

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

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.

Bentonite magma, calcium hydroxide, glycerin, purified water.

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	
Stop use and ask a doctor 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.	
Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center 1-800-222-1222 immediately.	
Continued ▶	

✓ QUALITY GUARANTEED

NDC 36800-702-96



Calamine Lotion USP

CALAMINE
TOPICAL SUSPENSION USP

Drying Lotion for:
Poison Ivy,
Oak & Sumac

6 FL OZ (177 mL)

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 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, Carageenan, Glycerin, Purified Water, and Xanthan Gum



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or call
1-888-423-0139

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

Stop use and ask a doctor 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.

Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center 1-800-222-1222 immediately.

Continued >

NDC 36800-702-08



Calamine Lotion USP

CALAMINE
TOPICAL SUSPENSION USP

Drying Lotion for:
Poison Ivy,
Oak & Sumac



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 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, Carageenan, Glycerin, Purified Water, and Xanthan Gum

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✓ QUALITY GUARANTEED

6 FL OZ (177 mL)

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 7 years of age

When using this product Discontinue use if condition worsens, does not improve, 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 36800-000-03



Calamine Lotion USP

CALAMINE
TOPICAL SUSPENSION USP

Drying Lotion for:
Poison Ivy,
Oak & Sumac



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 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, Carageenan, Glycerin, Purified Water, and Xanthan Gum

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✓ QUALITY GUARANTEED

6 FL OZ (177 mL)

TOPCARE CALAMINE

calamine 8% and zinc oxide 8% lotion lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-702
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)	
WATER (UNII: 059QF0KO0R)	
CALCIUM HYDROXIDE (UNII: PF5DZW74VN)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-702-96	177 mL in 1 CONTAINER; Type 0: Not a Combination Product	07/16/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M016	07/16/2019	

Labeler - TOPCO ASSOCIATES LLC (006935977)

Registrant - Pharma Nobis, LLC (118564114)

Establishment

Name	Address	ID/FEI	Business Operations
Pharma Nobis, LLC		118564114	analysis(36800-702) , manufacture(36800-702) , label(36800-702) , pack(36800-702)

Revised: 12/2023

TOPCO ASSOCIATES LLC