# **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.

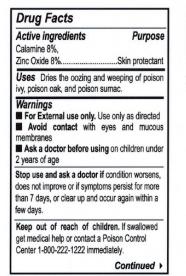
Ask a doctor before using on chilren 2 years of age.

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

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



**✓QUALITY GUARANTEED** 





R081921 0 36800 38432 3

DISTRIBUTED BY TOPCO ASSOCIATES LLC ELK GROVE VILLAGE, IL 60007© TOPCO HHGA0521 QUESTIONS? 1-888-423-0139 topcare@topco.com www.topcarebrand.com



Scan here for more information or call 1-888-423-0139

6 FL 0Z (177 mL)



2 years of age

Stop use and ask a doctor if condition worsers,
does not improve or if symptoms pessist for more
than 7 days, or clear up and converges in within a

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 1

+TopCare
health

# 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 cicth, 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).

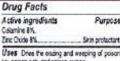
### Inactive ingredients

Avicel, Bentonite Magma, Calcium Hydroxide, Carageenan, Glycerin, Purified Water, and Xanthan Gum



ELK GROVE VILLAGE, IL 60007 GOTOPCO HHGADS QUESTIONS? 1-888-423-0139 bacare@topco.com www.topcarebrand.com Visit here for more information: http://loopbmds.com/48ouhd

6 FL OZ (177 mL)



ly, poison eak, and poison suring:

Warnings

■ For External use only. Use only as directed

 Avoid contact with eyes and mucous numbranes
 Ask a doctor before using on children under

? years of age
When using this product Decontinue use if operation worsers, does not improve, if symptoms persist for more than ? days, or dear up and occur again within a low days, and consult a does.

Keep out of reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately. +TopCare

## Calamine Lotion USP

CALAMINE TOPICAL SUSPENSION USP

Drying Lotion for: Poison Ivy, Oak & Sumac

6 FL 0Z (177 mL)



Drug Facts (CONTENUED)
Directions

Adults and children 2 years of age and older. Shake well before using. Cleanse the skin with scap and waker and let dry before each use. Apply lotton to the affected area using octors 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, Bertonite Magma, Calcium
Hydroxde, Carageenan, Glycerin,
Purified Water, and Xanthas Gum

FR061219

WHI JPS CHIMAN DON PESTERS MAY

WHI JPS CHIMAN SHAPE PESTERS MAY

O 36800 38432

DEFRONTED BY TUPOD ASCOMES LIC

SE APAPE ALLASE, LOOSE OF ORDORD HEARING

DESCRIPTION 180425 CLB

DESCRIPTION 180425 CLB

DESCRIPTION OF THE PESTERS MAY NOT THE PESTERS MAY NO

## 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

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							
#	tem 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