

**CALAMINE- calamine and zinc oxide lotion**  
**Strategic Sourcing Services, LLC**

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**Foster & Thrive Calamine Lotion**

Drug Facts

**Active Ingredients**

Calamine 8% and Zinc Oxide 8%

**Uses**

Dries the oozing and weeping of poison ivy, poison oak, and poison sumac.

**Purpose**

Skin protectant

**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 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.

**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, not more than 3 to 4 times daily 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

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

## Questions

Questions? 833-358-6431

NDC 70677-1196-1

Foster & Thrive™

**Calamine Lotion**

Calamine 8%  
Zinc Oxide 8%

**CALAMINE TOPICAL SUSPENSION USP  
SKIN PROTECTANT**

6 FL OZ (177 mL)

Drug Facts		Drug Facts (continued)
<b>Active Ingredients</b>	<b>Purpose</b>	<b>Directions</b>
Calamine 8%.....Skin protectant		<b>Adults and children 2 years of age and older:</b> Shake well before using. Cleanse the skin with soap and water and dry the area before application. Apply lotion to the affected area using cotton or soft cloth, as often as needed for comfort.
Zinc Oxide 8%.....Skin protectant		<b>Children under 2 years of age:</b> Consult a doctor before use.
<b>Uses</b> Dries the oozing and weeping of • poison ivy • poison oak • and poison sumac.		<b>Other Information</b> Store at room temperature 15°-30°C (50°-86°F)
<b>Warnings</b> <b>For external use only.</b> • Use only as directed. • Avoid contact with eyes and mucous membranes.		<b>Inactive ingredients</b> Bentonite Magma, Calcium Hydroxide, Carrageenan, Glycerin, Microcrystalline Cellulose, Purified Water, and Xanthan Gum.
<b>Stop use and ask a doctor if</b> • condition worsens • symptoms last more than 7 days or clear up and occur again within a few days.		<b>Questions?</b> Call 833-358-6431
<b>Keep out of reach of children.</b> In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately. (1-800-222-1222)		© 2023 McKesson Corporation Distributed by: McKesson Corp. via SSSL, Memphis, TN 38141 Money Back Guarantee www.fosterandthrive.com

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## CALAMINE

calamine and zinc oxide lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70677-1196
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675) (FERRIC OXIDE RED - UNII:1K09F3G675)	FERRIC OXIDE RED	80 mg in 1 mL
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	80 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>BENTONITE</b> (UNII: A3N5ZCN45C)	

<b>CARRAGEENAN</b> (UNII: 5C69YCD2YJ)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>CALCIUM HYDROXIDE</b> (UNII: PF5DZW74VN)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70677-1196-1	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/14/2024	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M016	09/14/2024	

**Labeler** - Strategic Sourcing Services, LLC (116956644)

**Registrant** - Pharma Nobis, LLC (118564114)

### Establishment

Name	Address	ID/FEI	Business Operations
Pharma Nobis, LLC		118564114	label(70677-1196) , manufacture(70677-1196) , analysis(70677-1196) , pack(70677-1196)

Revised: 9/2024

Strategic Sourcing Services, LLC