

TOPCARE CALAGESIC- calamine and pramoxine hydrochloride lotion
TOPCO ASSOCIATES LLC

Top Care Calagesic Lotion

Calamine 8%

Pramoxine Hydrochloride 1%

Skin Protectant

External analgesic

Dries the oozing and weeping, and temporarily relieves pain and itching of poison ivy, oak, and sumac or other skin irritations.

For external use only. Use only as directed.

When using this product. Avoid contact with eyes and mucous membranes.

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

Adults and children 2 yr. of age and older. Shake well before using. Cleanse the skin with soap and water and let dry. Apply to the affected area using cotton or soft cloth, not more than 3 to 4 times daily as needed for comfort.

Children under 2 yrs. of age. Consult a doctor before use.

SD Alcohol 38B 2.5%, Camphor, Diazolidinyl Urea, Fragrances, Glycerin, Hydroxypropyl Methycelulose, Methylparaben, Polysorbate 80, Propylene Glycol, Propylparaben and Purified Water.

NDC 36800-268-96

TopCare
health

COMPARE TO
CALADRYL[®] LOTION
ACTIVE INGREDIENT*

Calagesic Lotion

EXTERNAL ANALGESIC
SKIN PROTECTANT

Relieves Itching Due to:

- Poison Ivy
- Poison Oak
- Insect Bites
- Minor Skin Irritations

6 FL. OZ (177 mL)

Drug Facts	
Active ingredients	Purpose
Calamine 8%.....	Skin protectant
Pramoxine HCl 1%.....	External analgesic
Uses Dries the oozing and weeping and temporarily relieves pain and itching of poison ivy, poison oak, and poison sumac or other minor skin irritations.	
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.	
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, 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 15-30°C (59-86°F)	
Inactive ingredients SD Alcohol 38B 2.5%, Camphor, Diazolidinyl Urea, Fragrances, Glycerin, Hydroxypropyl Methycelulose, Methylparaben, Polysorbate 80, Propylene Glycol, Propylparaben, Purified Water	

✓ QUALITY GUARANTEED

*This product is not manufactured or distributed by Valeant Pharmaceuticals, owner of the registered trademark Caladryl[®] Lotion.



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

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NDC 36800-268-96



COMPARE TO CALADRYL® LOTION ACTIVE INGREDIENT*

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 QUESTIONS? 1-888-423-0139
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 Visit here for more information:
<http://topbrnds.com/46zult>
 ✓ QUALITY GUARANTEED



TOPCARE CALAGESIC

calamine and pramoxine hydrochloride lotion lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-268
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	80 mg in 1 mL
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
CAMPHOR (NATURAL) (UNII: N20HL7Q941)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
WATER (UNII: 059QF0KO0R)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-268-96	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(36800-268) , pack(36800-268) , label(36800-268) , manufacture(36800-268)

Revised: 12/2023

TOPCO ASSOCIATES LLC