TOPCARE CALACLEAR- pramoxine hydrochloride and zinc acetate lotion lotion
TOPCO ASSOCIATES LLC

Top Care Calaclear Lotion

Pramoxine HCl 1%

Zing Acetate 0.1%

External Analgesic

Skin Protectant

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

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.

Adults and children 2 yrs. 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.

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

In case of accidental ingestion, seek professional assistance or contact a poison control center immediately.

NDC 36800-267-96

TopCare health

COMPARE TO CALADRYL® CLEAR® LOTION ACTIVE INGREDIENT*

Calaclear Lotion

TOPICAL 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
Pramoxine HCl 1%	External analgesic
Zinc Acetate 0.1%	Skin protectant

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 Methylcellulose, 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® Clear Lotion.

R083021

0 36800 44340 2

DISTRIBUTED BY
TOPCO ASSOCIATES LLC
ELK GROVE VILLAGE, IL 60007
©TOPCO HH640321
QUESTIONS? 1-888-423-0139
topcare@topco.com
www.topcarebrand.com

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

NDC 36800-267-96

TopCare health

COMPARE TO CALADRYL® CLEAR® LOTION ACTIVE INGREDIENT*

Calaclear Lotion

TOPICAL ANALGESIC
SKIN PROTECTANT

Relieves Itching Due to:
- Poison Ivy
- Poison Oak
- Insect Bites
- Minor Skin Irritations

OUR PHARMACISTS RECOMMEND

6 FL OZ (177 mL)

Drug Facts

Active ingredients — Purpose
Pramoxine HCl 1% — External analgesic
Zinc Acetate 0.1% — Skin protectant

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 Methylcellulose, Methylparaben, Polysorbate 80, Propylene Glycol, Propylparaben, Purified Water

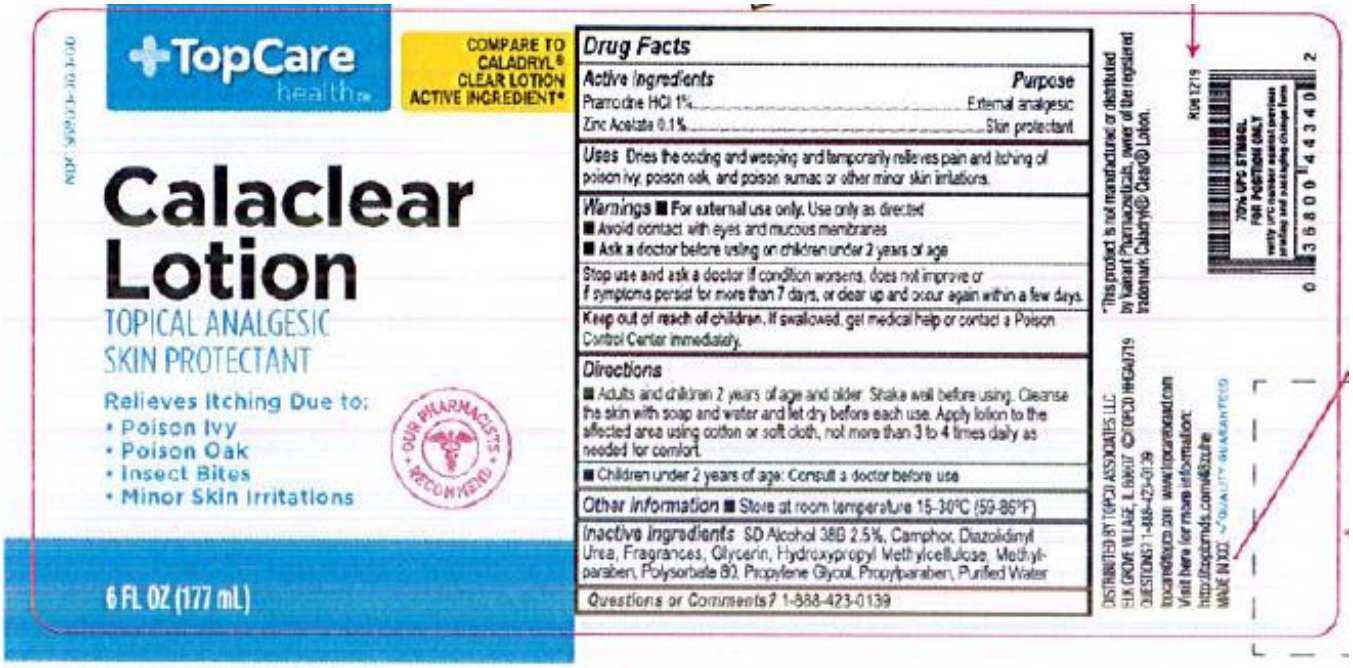
*This product is not manufactured or distributed by Valeant Pharmaceuticals, owner of the registered trademark Caladryl® Clear® Lotion.

R082819

0 36800 44340 2

DISTRIBUTED BY TOPCO ASSOCIATES LLC
ELK GROVE VILLAGE, IL 60007 ©TOPCO HH640819
QUESTIONS? 1-888-423-0139
topcare@topco.com www.topcarebrand.com
Visit here for more information:
http://topbrnds.com/48suhe

QUALITY GUARANTEED



TOPCARE CALACLEAR

pramoxine hydrochloride and zinc acetate lotion lotion

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:36800-267
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	10 mg in 1 mL
ZINC ACETATE (UNII: FM5526K07A) (ZINC CATION - UNII:13S1S8SF37)	ZINC ACETATE	1 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CAMPHOR (NATURAL) (UNII: N20HL7Q941)	
ALCOHOL (UNII: 3K9958V90M)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-267-96	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	manufacture(36800-267) , label(36800-267) , analysis(36800-267) , pack(36800-267)

Revised: 12/2023 TOPCO ASSOCIATES LLC