

CALAMINE CLEAR- pramoxine hydrochloride and zinc acetate lotion lotion
Cardinal Health, 110 dba Leader

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Leader Calamine Clear

Pramoxine HCl 1%

Zinc Acetate 0.1%

External Analgesic & Skin Protectant

Temporarily Relieves Pain and Itching Associated with:

rashes due to poison ivy, poison oak, or poison sumac

insect bites

minor skin irritation

minor cuts

dries the oozing and weeping of poison ivy, poison oak and poison sumac

For external use only. Use only as directed.

Acid contact with eyes and mucous membranes

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

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

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.

SD Alcohol 38B 2.5%

Camphor

Diazolidinyl Urea

Fragrances

Glycerin

Hydroxypropyl Methylcellulose

Methylparaben

Polysorbate 80

Propylene Glycol

Propylparaben

Purified Water

LEADER²

NDC 70000-0397-1

Calamine Clear Lotion

External Analgesic | Skin Protectant

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

COMPARE TO CALADRYL[®] CLEAR[®] LOTION active ingredients*

100% Money Back Guarantee

6 FL OZ (177 mL)

Drug Facts	
Active ingredients	Purpose
Pramoxine HCl 1%.....	External analgesic
Zinc Acetate 0.1%.....	Skin protectant
Uses	
<ul style="list-style-type: none"> ■ temporarily relieves pain and itching associated with: <ul style="list-style-type: none"> ■ rashes due to poison ivy, poison oak or poison sumac ■ insect bites ■ minor skin irritation ■ minor cuts ■ 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 immediately (1-800-222-1222).	
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.	
Questions or Comments? 1-800-662-3435	

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

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CARDINAL HEALTH
DUBLIN, OHIO 43007
www.myleader.com
1-800-200-6333

CIN 5455795 REV. 12/18

100% Money Back Guarantee

Return to place of purchase.

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CALAMINE CLEAR			
pramoxine hydrochloride and zinc acetate lotion			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0397
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	
	DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)		
	POLYSORBATE 80 (UNII: 6OZP39ZG8H)		
	CAMPHOR (NATURAL) (UNII: N20HL7Q941)		
	ALCOHOL (UNII: 3K9958V90M)		
	GLYCERIN (UNII: PDC6A3C0OX)		
	HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)		
	METHYLPARABEN (UNII: A2I8C7HI9T)		
	PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
	WATER (UNII: 059QF0KO0R)		
	PROPYLPARABEN (UNII: Z8IX2SC1OH)		

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0397-1	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/15/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	01/15/2019	

Labeler - Cardinal Health, 110 dba Leader (063997360)

Revised: 3/2022

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