LEADER CALAMINE PLUS- zinc oxide lotion lotion Cardinal Health, 110 dba Leader

LEADER Calamine Plus

- For external use only
- Avoid contact with eyes and mucous membranes
- Ask a doctor before using on children under 2 years of age

Calamine 8%

Pramoxine HCl 1%

- Skin Protectant
- External Analgesic

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 of 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.

SH Alcohol 38B 2.5%

Camphor

Diazolidinyl Urea

Fragrances

Glycerin

Hydroxypropyl Methylcellulose

Methylparaben

Polysorbate 80

Propylene Glycol

Propylparabaren

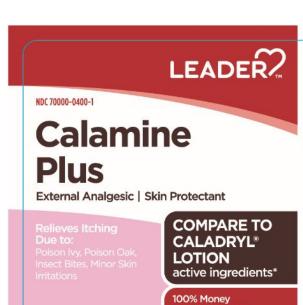
Purified water

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

Uses:

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



Back Guarantee

6 FL OZ (177 mL

Drug Facts Active ingredients..Purpose Calamine 8% Skin protectant Pramoxine HCI 1% External analgesic Uses ■ 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 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.

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.

Keep out of reach of children. If swallowed, get medical help or contact a Poison

■ 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, Methyl-paraben, Polysorbate 80, Propylene Glycol, Propylparaben, Purified Water.

Questions or Comments? 1-800-662-3435

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LEADER CALAMINE PLUS

zinc oxide lotion lotion

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:70000-0400 **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			
ALCOHOL (UNII: 3K9958V90M)				
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)				
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
HYPROMELLOSES (UNII: 3NXW29V3WO)				
GLYCERIN (UNII: PDC6A3C0OX)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
POLYSORBATE 80 (UNII: 60ZP39ZG8H)				
WATER (UNII: 059QF0KO0R)				

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
		177 mL in 1 CONTAINER; Type 0: Not a Combination Product	02/15/2019		
Marketing Information					
	Marketing	Application Number or Monograph	Marketing Start	Marketing End	
	Category	Citation	Date	Date	
ОТ	C Monograph Dru	M016	02/15/2019		

Labeler - Cardinal Health, 110 dba Leader (063997360)

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