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.

Acoid 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 fo the affected area using cotton or soft cloth, not more than 3 to 4 times dialy as needed for comfort.

SD Alcohol 38B 2.5%

Camphor

Diazolidinyl Usea

Fragrances

Glycerin

Hydroxypropyl Methylcellulose

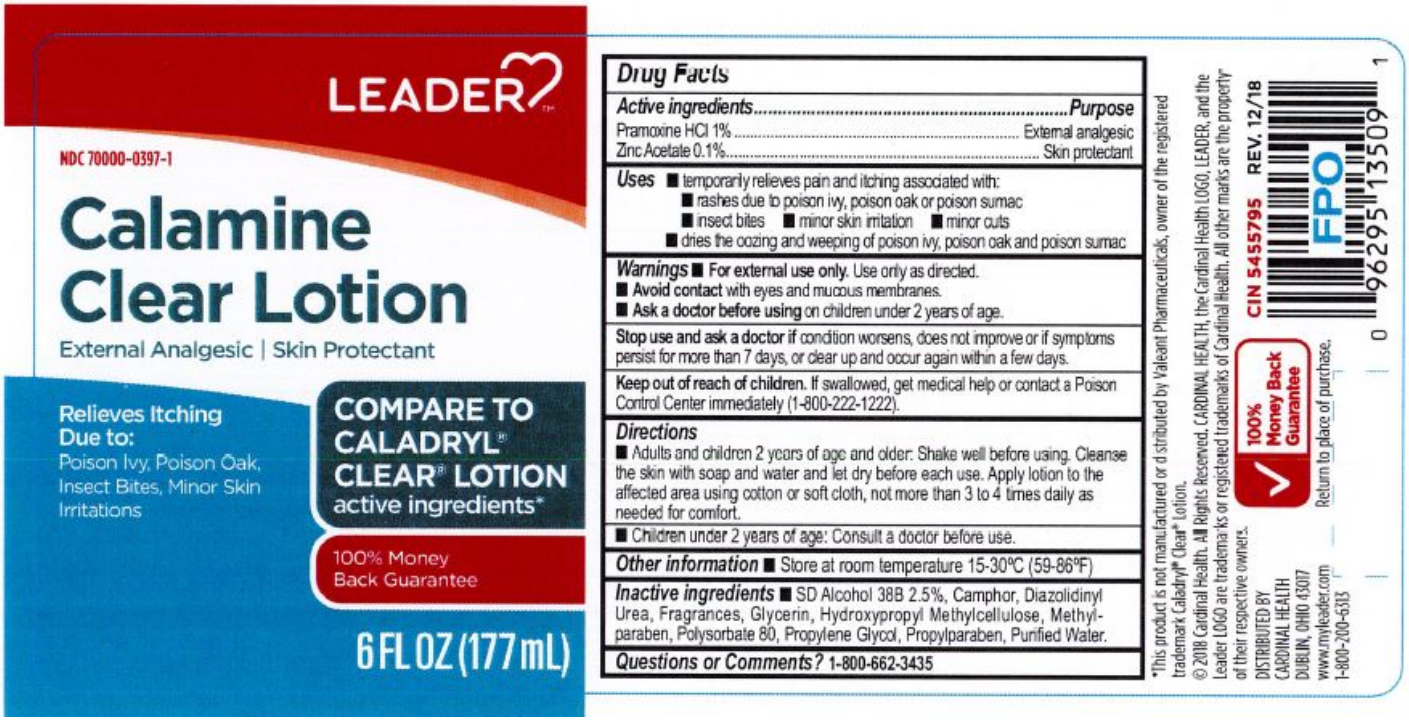
Methylparaben

Polysorbate 80

Propylene Glycol

Propylparaben

Purified Water



CALAMINE CLEAR

pramoxine hydrochloride and zinc acetate lotion 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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