CALADRYL CLEAR- pramoxine hydrochloride and zinc acetate lotion Bausch Health US, LLC

Caladryl Clear

Drug Facts

Active ingredients Purpose

Pramoxine HCl 1% Topical analgesic Zinc acetate 0.1% Skin protectant

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.

When using this product do not get into eyes

Stop use and ask a doctor if

- condition worsens or does not improve within 7 days
- 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 right away.

Directions

- shake well before use
- adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily
- children under 2 years of age: ask a doctor

Other information

• store at 20° to 25°C (68° to 77°F)

Inactive ingredients

SD alcohol 38-B, camphor, citric acid, diazolidinyl urea, fragrance, glycerin,

hypromellose, methylparaben, polysorbate 40, propylene glycol, propylparaben, purified water, sodium citrate

Questions/Comments

call **1-800-321-4576**

Distributed by: Bausch Health US, LLC, Bridgewater, NJ 08807 USA

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Rev. 01/2020 Made in Canada

PRINCIPAL DISPLAY PANEL - 177 mL Bottle Label

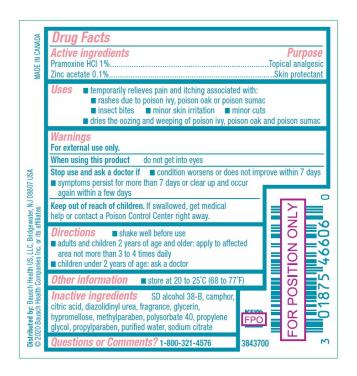
Caladryl [®] Clear [®]

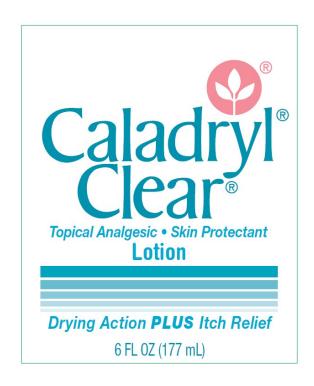
Topical Analgesic • Skin Protectant

Lotion

Drying Action **PLUS**Itch Relief

6 FL OZ (177 mL)





CALADRYL CLEAR

pramoxine hydrochloride and zinc acetate lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0187-5466
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	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)		
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)		
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)		
GLYCERIN (UNII: PDC6A3C0OX)		
METHYLPARABEN (UNII: A2I8C7HI9T)		
POLYSORBATE 40 (UNII: STI11B5A2X)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
PROPYLPARABEN (UNII: Z8IX2SC1OH)		
WATER (UNII: 059QF0KO0R)		
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)		
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)		

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:0187- 5466-06	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/16/2013	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M014	08/16/2013		
3 1 3				

Labeler - Bausch Health US, LLC (831922468)

Establishment				
Name	Address	ID/FEI	Business Operations	
Trillium Health Care Products Inc.		255426306	manufacture(0187-5466)	

Revised: 10/2024 Bausch Health US, LLC