

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

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**Caladryl Clear**

***Drug Facts***

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**Active ingredients Purpose**

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

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**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<sup>®</sup>**  
**Clear<sup>®</sup>**

*Topical Analgesic • Skin Protectant*  
**Lotion**

*Drying Action **PLUS** Itch Relief*

6 FL OZ (177 mL)

MADE IN CANADA

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FOR POSITION ONLY

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## CALADRYL CLEAR

pramoxine hydrochloride and zinc acetate lotion

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0187-5466
<b>Route of Administration</b>	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
<b>CAMPHOR (SYNTHETIC)</b> (UNII: 5TJD82A1ET)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>DIAZOLIDINYL UREA</b> (UNII: H5RIZ3MPW4)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>POLYSORBATE 40</b> (UNII: STI11B5A2X)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>SODIUM CITRATE, UNSPECIFIED FORM</b> (UNII: 1Q73Q2JULR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	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	

Labeler - Bausch Health US, LLC (831922468)

Establishment

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