CALADRYL- ferric oxide red, zinc oxide, and pramoxine hydrochloride lotion
Bausch Health US, LLC

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.

Caladryl Pink

Drug Facts

Active ingredients	Purpose
Calamine 8%	Skin protectant
Pramoxine HCl 1%	Topical 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.

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, diazolidinyl urea, fragrance, hypromellose, methylparaben, polysorbate 80, propylene glycol, propylparaben, purified water, xanthan gum

Questions/Comments

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

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

Rev. 01/2020

Made in Canada

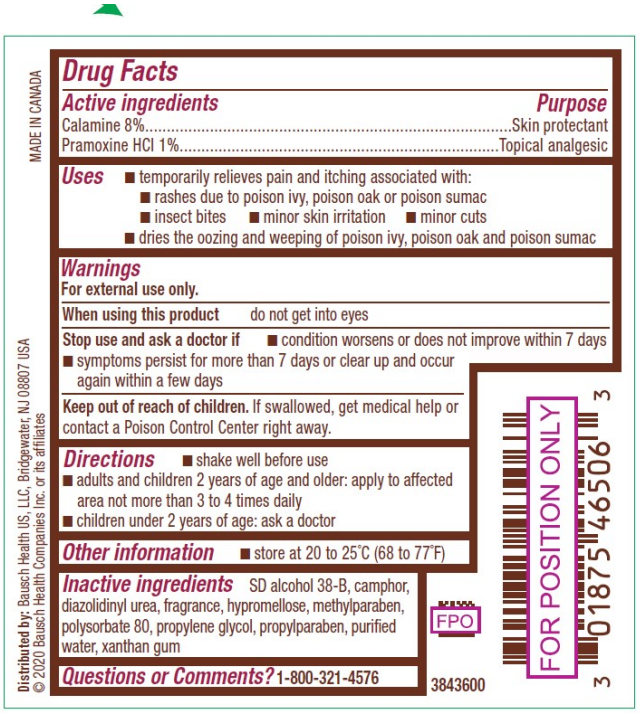
PRINCIPAL DISPLAY PANEL - 177 mL Bottle Label

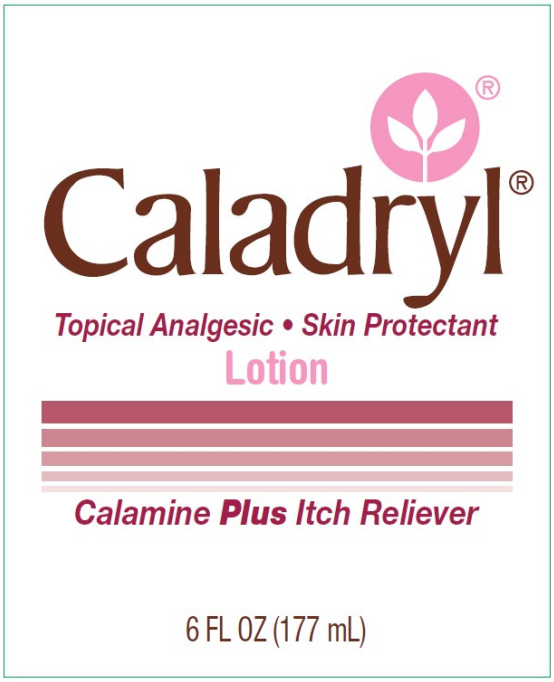
Caladryl®

Topical Analgesic • Skin Protectant
Lotion

*Calamine **Plus** Itch Reliever*

6 FL OZ (177 mL)





CALADRYL

ferric oxide red, zinc oxide, and pramoxine hydrochloride lotion

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0187-5465
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Ferric Oxide Red (UNII: 1K09F3G675) (Ferric Oxide Red - UNII:1K09F3G675)	Ferric Oxide Red	1.36 mg in 1 mL
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	78.65 mg in 1 mL
Pramoxine Hydrochloride (UNII: 88AYB867L5) (Pramoxine - UNII:068X84E056)	Pramoxine Hydrochloride	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Camphor (Synthetic) (UNII: 5TJD82A1ET)	
Diazolidinyl Urea (UNII: H5RIZ3MPW4)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
Methylparaben (UNII: A2I8C7HI9T)	
Polysorbate 80 (UNII: 6OZP39ZG8H)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Propylparaben (UNII: Z8IX2SC1OH)	
Water (UNII: 059QF0KO0R)	
Xanthan Gum (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0187-5465-06	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 final	part347	08/16/2013	

Labeler - Bausch Health US, LLC (831922468)

Establishment

Name	Address	ID/FEI	Business Operations
Trillium Health Care Products Inc.		255426306	MANUFACTURE(0187-5465)

Revised: 1/2020

Bausch Health US, LLC