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

©2020 Bausch Health Companies Inc. or its affiliates

Rev. 01/2020

Made in Canada

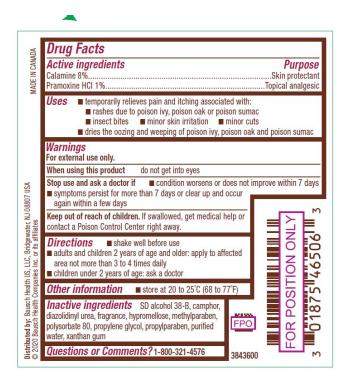
PRINCIPAL DISPLAY PANEL - 177 mL Bottle Label

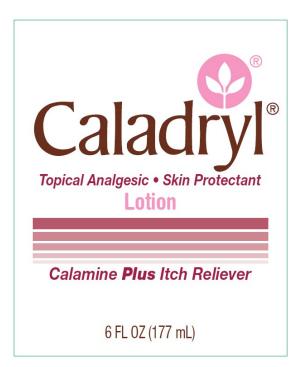
Caladryl®

Topical Analgesic \cdot Skin Protectant Lotion

Calamine Plus Itch Reliever

6 FL OZ (177 mL)





CALADRYL ferric oxide red, zinc oxide, and p=moxine hydrochloride lotion Product Information Product Type HUMAN OTC DRUG Route of Administration TOPICAL

0	ent/A	Active Moiety					
Ingredient Name				Basis of Strength	n Strength		
Ferric Oxide Red (ic 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 m		
Pramoxine Hydroc	hlori	de (UNII: 88AYB867L5) (Pramoxine - UNII:068X84E056	6)	Pramoxine Hydrochlori	de 10 mg in 1 mL		
Inactive Ingred	lie nt	S					
Ingredient Name							
Camphor (Synthet							
Diazolidinyl Urea (UNII: H5RIZ3MPW4)							
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)							
Methylparaben (UNII: A2I8C7HI9T)							
Polysorbate 80 (UN	√II: 6 C)ZP39ZG8H)					
Propylene Glycol (UNII:	6DC9Q167V3)					
Propylparaben (UN	VII: Z8	IX2SC1OH)					
Water (UNII: 059QF0K00R)							
Xanthan Gum (UNI		/12P4NEE)					
,	11						
,				Markating Start	Madating Fad		
Packaging		Package Description		Marketing Start Date	Marketing End Date		
Packaging # Item Code	177	Package Description mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination duct	0	U	U		
Packaging # Item Code 1 NDC:0187-5465-	177	mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination	0	Date	U		
Packaging # Item Code 1 NDC:0187-5465-	177 Pro	mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination duct	0	Date	U		
Packaging # Item Code 1 NDC:0187-5465- 06	177 Pro nfo 1	mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination duct	U	Date 8/16/2013	U		

Labeler - Bausch Health US, LLC (831922488)

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

Revised: 1/2020

Bausch Health US, LLC