CALAMINE- calamine, pramoxind hcl lotion
Consumer Product Partners, LLC

Good Sense 336.003/336AG
Medicated Calamine Lotion

Active ingredients

Calamine 8%

Pramoxine HCl 1%

Purpose

Skin protectant

External analgesic

Uses

- for the temporary relief of pain and itching associated with minot skin irritations and rashes due to poison ivy, poison oak, or poison sumac
- dries the oozing and weeping of poison: -ivy -oak -sumac

Warnings

For external use only

When using this product

- do not get into eyes

Stop use and ask a doctor if

- condition worsens
- symptoms last more than 7 days or clean 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 applying was affected are of skin

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 - do not use, ask a doctor

Other information

store at room temperature (59°-77°F)

Inactive ingredients

alcohol, benzyl alcohol, camphor, fragrance, hydroxypropyl methylcellulose, Lavandula angustifolia (lavender) oil, phenoxyethanol, polysorbate 80, propylene glycol, Rosmarinus officinalis (rosemary) leaf oil, water, xanthan gum

Disclaimer

*This product is not manufactured or distributed by Bausch Health US, LLC, distributor of Caladryl Lotion Calamine Plus Itch Reliever.

Adverse reaction

Distributed by Perrigo Direct, Inc.

Peachtree City, GA 30269

www.PerrigoDirect.com

1-888-593-0593

Good Sense is a registered trademark of L. Perrigo Company

Principal display panel

NDC 11344-336-30

GoodSense

MEDICATED

Calamine Itch Relief Lotion

EXTERNAL ANALGESIC/SKIN PROTECTANT

Pain and itch reliever

Compare to active ingredients of Caladryl Lotion*

6 FL OZ (177 mL)

CALAMINE

calamine, pramoxind hcl lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11344-336
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	80 mg in 1 mL
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	10 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ALCOHOL (UNII: 3K9958V90M)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ROSEMARY OIL (UNII: 8LGU7VM393)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11344-336-30	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/08/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M016	09/08/2016	

Labeler - Consumer Product Partners, LLC (119091520)

Registrant - Consumer Product Partners, LLC (119091520)

Establishment

Name	Address	ID/FEI	Business Operations
Consumer Product Partners, LLC		119091514	manufacture(11344-336)

Revised: 3/2024 Consumer Product Partners, LLC