CALAMINE PLUS- calamine plus pramoxine hcl aerosol, spray Meijer Distribution Inc.

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.

Meijer Calamine Plus Spray

Active ingredients

Calamine 8%

Pramoxine HCI 1%

Purpose

Skin protectant

External analgesic

Uses

temporarily relieves pain and itching associated with:

- insect bites
- rashes
- minor skin irritations
- minor cuts
- dries the oozing and weeping of poison ivy, poison oak and poison sumac

Warnings

For external use only.

Flammable:

Do not use while smoking or near heat or flame. Do not puncture or incinerate. Contents under pressure. Do not store at temperatures above 120°F. Intentional misuse by deliberately concentrating and inhaling contents can be harmful or fatal.

When using this product

- do not get into eyes
- ask a doctor before using on children under 2 years of age

Stop use and ask a doctor if

- condition worsens
- symptoms last more than 7 days or clear up and occur again in a few days

Keep out of the reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- shake well before using
- adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily
- cleanse the skin with soap and water
- let dry before use
- children under 2 years of age: consult a doctor

Other Information

store between 20° to 25°C (68° to 77°F)

Inactive ingredients

benzyl alcohol, camphor, disteardimonium hectorite, fragrance, hydrated silica, isobutane, oleyl alcohol, SD alcohol 40-B, sorbitan trioleate

Questions?

Call 1-866-964-0939

Principal Display Panel

meijer

NO-RUB

calamine plus spray

Calamine 8%/Skin Protectant

Pramoxine HCI 1%/External analgesic

Relieves itching from poison ivy, oak & sumac, & insect bites

Soothes minor skin irritations & cuts

SHAKE WELL BEFORE USE

NET WT 4.1 OZ (116 g)



CALAMINE PLUS SPRAY

PRAMOXINE HCI 1%/EXTERNAL ANALGESIC

COMPARE TO CALADRYL® LOTION ACTIVE INGREDIENTS

RELIEVES ITCHING FROM POISON IVY, OAK & SUMAC, & INSECT BITES

Soothes minor skin irritations & cuts

Shake well before use

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Drug Facts Active ingredients Purpose Calamine 8%...... Pramoxine HCl 1% Skin protectant External analgesic product is not manufactured or distributed by Bausch Health Ireland Ltd. ler of the registered trademark Caladry $|^{lpha}.$

Uses temporarily relieves pain and itching associated with:

■ insect bites ■ rashes ■ minor skin irritations ■ minor cuts

■ dries the oozing and weeping of poison ivy, poison oak and poison sumac

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MADE IN USA WITH U.S. AND IMPORTED PARTS





50-074ME-01

CALAMINE PLUS

calamine plus pramoxine hcl aerosol, spray

Product Information

Product Type HUMAN OTC DRUG **Item Code (Source)** NDC:79481-0615

This

TOPICAL Route of Administration

Active Ingredient/Active Moiety Ingredient Name Basis of Strength Strength FERRIC OXIDE RED (UNII: 1K09F3G675) (FERRIC OXIDE RED -FERRIC OXIDE RED 5 mg in 1 g UNII:1K09F3G675) PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE -**PRAMOXINE** 10 mg in 1 g UNII:068X84E056) **HYDROCHLORIDE** 79.5 mg ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) ZINC OXIDE in 1 g

Inactive Ingredients				
Ingredient Name	Strength			
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)				
ISOBUTANE (UNII: BXR49TP611)				
BENZYL ALCOHOL (UNII: LKG8494WBH)				
OLEYL ALCOHOL (UNII: 172F2WN8DV)				
SORBITAN TRIOLEATE (UNII: QE6F49RPJ1)				

ALCOHOL (UNII: 3K9958V90M)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	

l	Packagin	ackaging				
	# Item C	ode	Package Description	Marketing Start Date	Marketing End Date	
	1 NDC:7948 0615-1	1- 116 g in 1 Product	1 CANISTER; Type 0: Not a Combination	08/25/2023		

Marketing In	larketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph not final	part348	08/25/2023				

Labeler - Meijer Distribution Inc. (006959555)

Revised: 8/2023 Meijer Distribution Inc.