CALAMINE PLUS PRAMOXINE HCL- calamine plus spray aerosol, spray Foodhold USA

CareOne Calamine Plus Spray

Active Ingredient

Calamine 8% Pramoxine HCl 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 temperature above 120°F. Intentional misuse by delibrately 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

- conditions worsens
- symptoms last more than 7 days or clear up and occur again in 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 using
- adults and children 2 years of age and older: apply as needed to the affected area, not more than 3 or 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

CareOne

NO-RUB CALAMINE SPRAY

Calamine 8%/ Skin Protectant

Pramoxine HCl 1%/ External Analgesic

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

SOOTHES MINOR SKIN IRRITATIONS AND CUTS

Shake well before use

NET WT 4.1 OZ (116g)



CALAMINE PLUS PRAMOXINE HCL

calamine plus spray aerosol, spray

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-184
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	24.16 mg in 116 g	
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	2.72 mg in 116 g	
FERRIC OXIDE RED (UNII: 1K09F3G675) (FERRIC OXIDE RED - UNII:1K09F3G675)	FERRIC OXIDE RED	0.345 mg in 116 g	

Inactive Ingredients		
Ingredient Name	Strength	
HYDRATED SILICA (UNII: Y6O7T4G8P9)		
OLEYL ALCOHOL (UNII: 172F2WN8DV)		
ALCOHOL (UNII: 3K9958V90M)		
SORBITAN TRIOLEATE (UNII: QE6F49RPJ1)		
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)		

ISOBUTANE (UNII: BXR49TP611)		
BENZYL ALCOHOL (UNII: LKG8494WBH)		
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)		

ı	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:41520-184-	116 g in 1 CANISTER; Type 0: Not a Combination Product	02/01/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	02/01/2019	

Labeler - Foodhold USA (809183973)

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