CALAMINE PLUS PRAMOXINE HCL- calamine plus spray aerosol, spray
HY-VEE, 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.

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. Use only as directed. Intentional misuse by deliberately concentrating and inhailing 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
- symtomps 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

HyVee Health

Calamine Plan Spray

Calamine 8% - Skin Protectant

Promoxine HCL 1% - External Analgesic

Drying action plus itch relief

Ideal for: poison ivy/ oak/ sumac

insect bites, minor skin irritations & cuts

SHAKE WELL BEFORE USE

NET WT 4.1 OZ (116 g)

CALAMINE PLUS PRAMOXINE HCL

calamine plus spray aerosol, spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:42507-147
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	0.345 mg in 116 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	24.16 mg in 116 g
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	2.72 mg in 116 g

Inactive Ingredients	
Ingredient Name	**Strength**
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
ISOBUTANE (UNII: BXR49TP611)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
ALCOHOL (UNII: 3K9958V90M)	
SORBITAN TRIOLEATE (UNII: QE6F49RPJ1)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:42507-147-41	116 g in 1 CANISTER; Type 0: Not a Combination Product	12/22/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	12/22/2017	

Labeler - HY-VEE, INC (006925671)

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