

ITCH RELIEF CLEAR SKIN PROTECTANT CVS- pramoxine hcl, zinc acetate spray CVS

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.

Drug Facts

☐Active ingredient

Pramoxine HCl 1%

Zinc Acetate 0.1%

☐Purpose

Itch Relief.

☐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.

Flammable: Do not use near heat, flame, or while smoking.

☐☐

☐When using this product

- keep out of eyes. Rinse with water to remove.
- Do not puncture or incinerate. Contents under pressure. Do not store at temperatures above 120F.

☐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.

☐ Inactive ingredients

SD Alcohol 38-B, Avena Sativa (Oat Meal) Extract, Camphor, Citric Acid, Diazolidinyl Urea, Fragrance, Glycerin, Hypromellose, Methylparaben, Polysorbate 40, Propylene Glycol, Propylparaben, Sodium Citrate, Water.

CVS Continuous Spray Itch Relief

☐ Clear Skin Protectant

☐ 1% Pramoxine HCl

0.1% Zinc Acetate

ITCH RELIEF CLEAR SKIN PROTECTANT CVS			
pramoxine hcl, zinc acetate spray			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-295
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			

Ingredient Name	Basis of Strength	Strength
PRAMO XINE HYDRO CHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	1 g in 100 g
ZINC ACETATE (UNII: FM5526K07A) (ZINC CATION - UNII:13S1S8SF37)	ZINC ACETATE	.1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
OATMEAL (UNII: 8PI54V663Y)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
METHYL PARABEN (UNII: A2I8C7H9T)	
POLYSORBATE 40 (UNII: STI11B5A2X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-295-03	85 g in 1 CAN; Type 0: Not a Combination Product	10/31/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	10/31/2014	

Labeler - CVS (062312574)

Registrant - Product Quest Mfg, LLC (927768135)

Establishment

Name	Address	ID/FEI	Business Operations
Product Quest Mfg, LLC		927768135	manufacture(59779-295)