ITCH RELIEF MEDICATED PADS CVS- pramoxine hcl, zinc acetate liquid
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%	External Analgesic
Zinc Acetate 0.1%	Skin Pretectant

Uses

- Temporarily relieves pain and itching asociated 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.

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 with in a few days.

Keep out of reach of children

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

Directions

- 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

Avena Sativa (Oat) Meal Extract
Camphor
Citric Acid
Diazolidinyl Urea
Fragrance

Glycerin
Hydroxypropyl Methylcellulose
Methylparaben
Polysorbate 40
Propylene Glycol
Propylparaben
SD Alcohol 38-B
Sodium Citrate
Water

ITCH RELIEF MEDICATED PADS CVS

pramoxine hcl, zinc acetate liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69842-842
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
PRAMOXINE HYDROCHLORIDE (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)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 40 (UNII: STI11B5A2X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-842-03	69 g in 1 JAR; Type 0: Not a Combination Product	03/15/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	03/15/2017	

Labeler - CVS (062312574)

Registrant - Product Quest Mfg, LLC (927768135)

Establishment

Name	Address	ID/FEI	Business Operations
Product Quest Mfg, LLC		927768135	manufacture(69842-842)

Revised: 11/2017 CVS