

CLEAR ITCH RELIEF- pramoxine hcl, zinc acetate spray

TopCare

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 ingredients

Pramoxine HCl 1.0%.....Topical analgesic
Zinc Acetate 0.1%.....Skin protectant

Purpose

☐ Purpose

☐ 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

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.
CLEAR SKIN PROTECTANT
 Pramoxine HCl 1% - Topical Analgesic
 Zinc Acetate 0.1% - Skin Protectant
 Drying Action PLUS Itch Relief
 Continuous Spray
 Relieves Pain And Itch
 Associated Wit

Drug Facts

Active ingredients	Purpose
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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 while smoking or near heat or flame
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 120°F.
Stop use and ask 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 immediately.

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

Other information • store at 20° to 25°C (68° to 77°F)

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.

*This product is not manufactured or distributed by Johnson & Johnson Consumer Products Company, owner and distributor of the Caladryl® Clear® trademark

TopCare®

Clear Itch Relief Spray

CLEAR SKIN PROTECTANT

Pramoxine HCl 1% - Topical Analgesic
 Zinc Acetate 0.1% - Skin Protectant
 Drying Action PLUS Itch Relief
 Continuous Spray
Relieves Pain And Itch Associated With:

- Poison Ivy
- Oak Or Sumac Rash
- Insect Bites
- Minor Cuts

DISTRIBUTED BY
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Compare to Caladryl® Clear® active ingredients*

NET WT 3 OZ (85 g)

CLEAR ITCH RELIEF			
pramoxine hcl, zinc acetate spray			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-874
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: ST11B5A2X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-874-03	85 g in 1 CAN; Type 0: Not a Combination Product	01/22/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/22/2013	

Labeler - TopCare (006935977)**Registrant** - Product Quest Mfg, LLC (927768135)**Establishment**

Name	Address	ID/FEI	Business Operations
Product Quest Mfg, LLC		927768135	manufacture(36800-874) , label(36800-874)