

CLEAR ANTI ITCH- pramoxine hcl, zinc acetate lotion
TOPCO ASSOCIATES

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.

Top Care Clear Anti-Itch Lotion 218.002 / 218AF

Active Ingredients

Pramoxine HCl 1%

Zinc acetate 0.1%

Purpose

External analgesic

Skin protectant

Use

- for the temporary relief of pain and itching associated with minor skin irritations and rashes due to poison ivy, poison oak or poison sumac
- dries the oozing and weeping of poison:
 - ivy
 - oak
 - sumac

Warnings

For external use only

When using this product

do not get into eyes

Stop use and ask a doctor if

- condition worsens
- symptoms last 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 applying was affected are of skin

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 room temperature (59°-77°F)

Inactive ingredients

alcohol, benzoic acid, camphor, citric acid, fragrance, glycerin, hydroxypropyl methylcellulose, Lavandula angustifolia (lavender) oil, polysorbate 40, Rosmarinus officinalis (rosemary) leaf oil, sodium citrate, water

DISTRIBUTED BY TOPCO ASSOCIATES LLC, ELK GROVE VILLAGE, IL60007

TOPCP VIJA0622 Questions? 1-888-423-0139

topcare@topco.com www.topcarebrand.com

Visit here for more information: <http://topbrnds.com/4901jl>

This product is not manufactured of distributed by Bausch Health US, LLC,

Distributer of Caladryl Clear Lotion

Quality Guaranteed

principal display panel

TopCare health

NDC 36800-218-30

COMPARE TO CALADRYL CLEAR LOTION ACTIVE INGREDIENTS

Clear Anti-Itch Lotion

EXTERNAL ANALGESIC / SKIN PROTECTANT

For Relief of Pain and Itching Due To:

- Poison Ivy, Oak or Sumac
- Insect Bites
- Minor Skin Irritations

6 FL OZ (177 mL)

NDC 36800-218-30



COMPARE TO
CALADRYL®
CLEAR® LOTION
ACTIVE INGREDIENTS*

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6 FL OZ (177 mL)

CLEAR ANTI ITCH
pramoxine hcl, zinc acetate lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-218
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	10 mg in 1 mL
ZINC ACETATE (UNII: FM5526K07A) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	1 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
CAMPHOR (NATURAL) (UNII: N20HL7Q941)	

CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
glycerin (UNII: PDC6A3C0OX)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
POLYSORBATE 40 (UNII: STI11B5A2X)	
ROSEMARY OIL (UNII: 8LGU7VM393)	
sodium citrate (UNII: 1Q73Q2JULR)	
Water (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-218-30	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/03/2009	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	06/03/2009	

Labeler - TOPCO ASSOCIATES (006935977)

Registrant - Vi-Jon, LLC (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(36800-218)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(36800-218)