CLEAR ANTI-ITCH- pramoxine hcl, zinc acetate lotion DOLGENCORP, LLC

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.

Rexall 218.001-218AE Clear Itch Relief Lotion

Active ingredients

Pramoxine HCl 1%

Zinc acetate 0.1%

Purpose

External analgesic

Skin protectant

Uses

- 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 section 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 wash affected area 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 - ask a doctor

Other information

store at room temperature (59° - 77° F)

Inactive ingredients

alcohol, camphor, citric acid, diazolidinyl urea, fragrance, glycerin, hypromellose, methylparaben, oil of lavender, oil of rosemary, polysorbate 40, propylene glycol, propylparaben, purified water, sodium citrate

Adverse reaction

Visit us at: Rexall.com or call 1-866-4-REXALL

DISTRIBUTED BY OLD EAST MAIN CO.

100 Mission Ridge

Goodlettsville, TN 37072

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A0154

principal display panel

Since 1903

Rexall

Clear Antio-Itch Lotion

External Analgesic Skin Protectant

For relief from pain and itcing due to:

- Poison ivy, oak and sumac
- Insect bites
- Minor skin irritations

6 FL OZ (177 mL)



CLEAR ANTI-ITCH

pramoxine hcl, zinc acetate lotion

Product Information					
Product Type	HUMAN OTC DRUG	OTC DRUG Item Code (Source)		NDC:55910-218	
Route of Administration	TOPICAL				
Active Ingredient/Active	Moiety				
Ingredient Name Basis of Stree			ength	Strength	
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)			PRAMOXINE HYDROCHLORIDE		10 mg in 1 mL
ZINC ACETATE (UNII: FM5526K07A) (ZINC CATION - UNII:13S1S8SF37)			ZINC ACETATE		1 mg in 1 mL
Inactive Ingredients					
Ingredient Name				Strength	
ALCOHOL (UNII: 3K9958V90M)					
CAMPHOR (SYNTHETIC) (UNII: 5T	JD82A1ET)				
CITRIC ACID MONOHYDRATE (UN	III: 2968PHW8QP)				

DIAZOLIDINYL UREA (UNII: H5RIZ 3MPW4)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
ROSEMARY OIL (UNII: 8LGU7VM393)	
POLYSORBATE 40 (UNII: STI11B5A2X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC10H)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910- 218-30	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/30/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part347	06/30/2011	

Labeler - DOLGENCORP, LLC (068331990)

Registrant - Vi-Jon, LLC (790752542)

Establishment				
Name	Address	ID/FEI	Business Operations	
Vi-Jon, LLC		790752542	manufacture(55910-218)	
Establishment				

Latabilament				
Name	Address	ID/FEI	Business Operations	
Vi-Jon, LLC		088520668	manufacture(55910-218)	

Revised: 8/2022

DOLGENCORP, LLC