LEADER POISON IVY WASH- pramoxine hydrochloride lotion lotion Cardinal Health, 110 dba Leader

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.

LEADER Poison Ivy Wash

When using this product:

- avoid contact with eyes
- do not leave on skin longer than 3 minutes
- rinse thoroughly after application

Inactive Ingredients:

Water

Ammonium Lauryl Sulfate

Distearyl Phthalic Acid Amide

Glycol Distearate

Cocamide MIPA

Propylene Glycol

Diazolidinyl Urea

Methylparaben

Propylparaben Glycerin

Jojoba Esters

Disodium EDTA

Sodium Hydroxide

Nonxynol-9

Adults and children 2 years of age and older:

- Wet the affected area
- Apply product to affected skin and surrounding area
- work foam into a lather and rub for up to 3 minutes, if needed

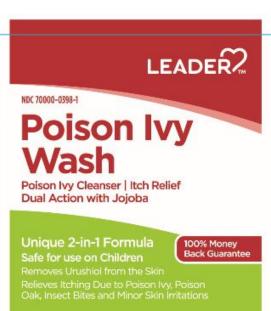
For temporary relief of pain and itching associated with poison ivy, poison oak, poison sumac.

Keep out of reach of children. In case of accidental ingestion, week professional assistance or contact a poison control center immediately. (1-800-222-1222)

External Analgesic

Pramoxine HCI 1%





Drug Facts (continued) Do not leave on skin for longer than 3 minutes. . Thoroughly rinse product from all areas. . Apply to affected area not more than 3 to 4 times daily

Children under 2 years of age: Consult a

Other information . For best results, use near a shower or sink where it is easy to thoroughly rinse off the product.

Inactive ingredients Ammonium Lauryl Sulfate, Distearyl Phthalic Acid Amide, Glycol Distearate, Cocamide MIPA, Propylene Glycol (and) Diazolidinyl Urea (and) Methylparaben (and) Propylparaben, Glycerin, Jojoba Esters, Disodium EDTA, Sodium Hydroxide, Nonxynol-9.

Removes urushiol (Poison Ivy Oil) from the skin. For best results use as soon as possible after contact with poison ivy is suspected.

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Guarantee

Return to place of purchase.

LEADER POISON IVY WASH

Continued |

pramoxine hydrochloride lotion lotion

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:70000-0398

6 FL OZ (177 mL)

Route of Administration TOPICAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength Strength PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE -**PRAMOXINE** 10 mg UNII:068X84E056) **HYDROCHLORIDE** in 1 mL

Inactive Ingredients			
Ingredient Name	Strength		
AMMONIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)			
PROPYLPARABEN (UNII: Z8IX2SC1OH)			
GLYCOL DISTEARATE (UNII: 13W7MDN21W)			
GLYCERIN (UNII: PDC6A3C0OX)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
SODIUM HYDROXIDE (UNII: 55X04QC32I)			
EDETATE DISODIUM (UNII: 7FLD91C86K)			
NONOXYNOL-9 (UNII: 48Q180SH9T)			
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)			
WATER (UNII: 059QF0KO0R)			
METHYLPARABEN (UNII: A2I8C7HI9T)			
HYDROLYZED JOJOBA ESTERS (ACID FORM) (UNII: UDR641JW8W)			

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:70000- 0398-1	177 mL in 1 CONTAINER; Type 0: Not a Combination Product	02/15/2019		

Marketing Information				
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
art348	02/15/2019			
	Application Number or Monograph Citation	Application Number or Monograph Marketing Start Citation Date		

Labeler - Cardinal Health, 110 dba Leader (063997360)

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