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

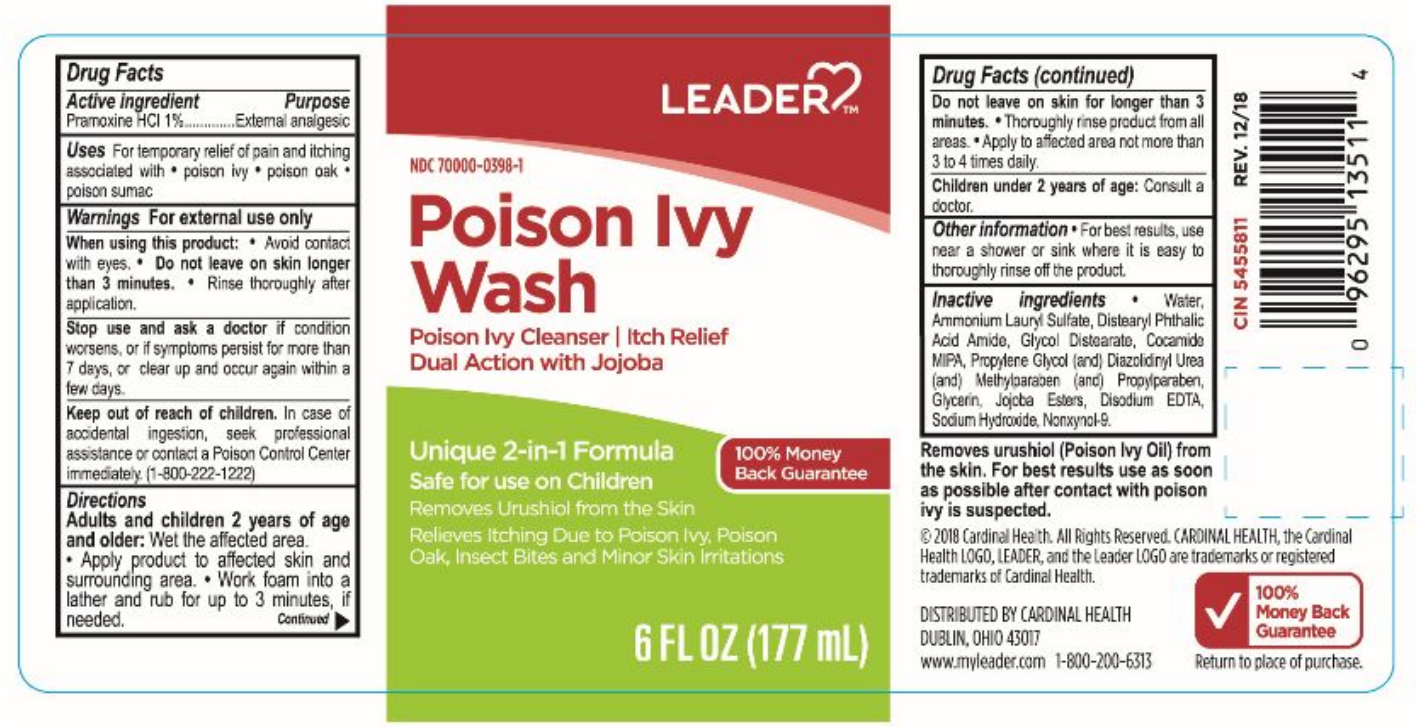
Adults and children 2 years of age and older:
- Wet the affected area
- Apply product to affected skin and surrounding area
- work foam into a lather and rub for up to 3 minutes, if needed

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 HCl 1%



LEADER POISON IVY WASH

pramoxine hydrochloride lotion lotion

Product Information

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

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

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	02/15/2019	

Labeler - Cardinal Health, 110 dba Leader (063997360)

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