

PRIVATE LABEL POISON IVY WASH- pramoxine hydrochloride lotion
Humco Holding Group, Inc.

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.

5th & Co. Poison Ivy Wash

Drug Facts

Active Ingredient

Pramoxine HCl 1%

Purpose

External analgesic

Uses

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

Warnings

For external use only

When using this product

Avoid contact with the eyes. Do not leave on skin longer than three minutes. Rinse thoroughly after application.

Stop use and ask a doctor if

conditions worsen or if symptoms persist for more than 7 days or clear up and occur again within a few days.

Directions

Adult and children 2 years of age and older. Wet affected areas. Apply the product to affected skin and surrounding area. Work foam into a lather and rub for up to 3 minutes, if needed. Do not leave on skin for longer than 3 minutes. Thoroughly rinse product from all areas. Apply to affected are not more than 3 to 4 times daily. Children under 2 years of age. Consult a doctor.

Other Information

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

Keep out of reach of children

Inactive Ingredients

Water, Ammonium Lauril Sulfate, Distearyl Phtalic Acid Amide, Glyco Distearate, Cocamide MIPA,

Propylene Glycol, (and) Diazolidinyl Urea (and) Methylparaben (and) Propylparaben, Glycerin, Jojoba Esters, Disodium EDTA, Sodium Hydroxide, Nonoxynol-9.

Questions or Comments?

1-800-662-3435

Removes Urushiol from the skin. For best results, use as soon as possible after contact with poison ivy is suspected.

5th & Co. Poison Ivy Wash



Drug Facts (continued)

Children under 2 years of age: Consult a doctor.

Other Information

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

Inactive Ingredients

Water, 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, Nonoxynol-9.

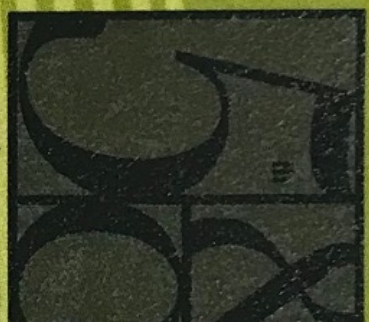
Questions or Comments? 1-800-662-3435

Removes urushiol from the skin. For best results, use as soon as possible after contact with poison ivy is suspected.

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Manufactured by: Humco
Texarkana, TX 75501 USA
1-800-662-3435

R053118



5th & Co.

POISON

IVY WASH

fast-acting itch
dual action with

Poison Ivy Clear

6 oz (177 mL)



Drug Facts

Active Ingredient **Purpose**
 Pramoxine HCl 1% External Analgesic

Uses For temporary relief of pain and itching associated with • poison ivy • poison oak • poison sumac

Warnings For external use only.

When using this product:

- Avoid contact with the eyes.
- Do not leave on skin longer than 3 minutes.
- Rinse thoroughly after application.

Stop use and ask a doctor if condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days.

Directions
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. **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.

Continued ▼

PRIVATE LABEL POISON IVY WASH

pramoxine hydrochloride lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0802-0119
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PRAMO XINE HYDRO CHLORIDE (UNII: 88 AYB867L5) (PRAMO XINE - UNII:068 X84E056)	PRAMO XINE HYDROCHLORIDE	1 mg in 1 mg

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0802-0119-96	117000 mg in 1 BOTTLE; Type 0: Not a Combination Product	06/18/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/18/2018	

Labeler - Humco Holding Group, Inc. (825672884)

Registrant - Humco Holding Group, Inc. (825672884)

Establishment

Name	Address	ID/FEI	Business Operations
Humco Holding Group, Inc.		825672884	manufacture(0802-0119) , pack(0802-0119) , label(0802-0119) , analysis(0802-0119)

Revised: 6/2020

Humco Holding Group, Inc.