

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.

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, 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 worsens 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 area not more than 3 to 4 times daily. Children under 2 years of age. Consult a doictor.

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 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.

Principal display panel

Dual Action with Jojoba. NDC 0395-0119-96. IVY WASH. POISON IVY CLEANSER. FAST ACTING ITCH RELIEF. SAFE FOR USE IN CHILDREN. SAFE FOR USE DURING PREGNACY. UNIQUE 2-IN-1 FORMULA. #1) Starts to work in seconds to remove Poison Ivy Oil (Urushiol), and helps minimize the damaging effects of Poison Ivy contamination. #2) Stops itching FAST. 6OZ (177 mL).

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
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Questions or Comments? ☎ 1-800-662-3435
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 HUMCO
 Distributed by:
 HUMCO, Texarkana, TX 75501

DUAL ACTION WITH JOJOBA
IVY WASH
POISON IVY CLEANSER
FAST ACTING ITCH RELIEF
 ✓ SAFE FOR USE ON CHILDREN
 ✓ SAFE FOR USE DURING PREGNACY
 6 OZ (177 mL)

NDC 0395-0119-96

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 ▶
 R120812.RLG

IVY WASH

pramoxine hydrochloride lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0395-0119
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	10 in 1 mL

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0395-0119-96	117 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/14/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/01/2008	

Labeler - Humco Holding Group, Inc. (825672884)

Registrant - Humco Holding Group, Inc. (825672884)

Establishment

Name	Address	ID/FEI	Business Operations
Humco Holding Group, Inc.		825672884	label(0395-0119) , manufacture(0395-0119) , pack(0395-0119) , analysis(0395-0119)

Revised: 12/2017

Humco Holding Group, Inc.