

# **ITCH X- benzyl alcohol/pramoxine hydrochloride gel**

## **BF ASCHER AND CO INC**

### **Itch-X Gel**

#### **Active ingredients.....Purpose**

Benzyl alcohol 10%.....Topical analgesic

Pramoxine hydrochloride 1%.....Topical analgesic

#### **Use**

Temporarily relieves pain and itching associated with insect bites, minor burns, sunburn, minor cuts, scrapes, minor skin irritations, hives and rashes due to poison ivy, poison oak, or poison sumac

#### **Use**

Temporarily relieves pain and itching associated with insect bites, minor burns, sunburn, minor cuts, scrapes, minor skin irritations, hives and rashes due to poison ivy, poison oak, or poison sumac

#### **Warnings**

- For external use only.
- Avoid contact with eyes.

#### **Do not use**

- on open wounds, damaged, or blistered skin.
- for vaginal, genital, or rectal itching.
- on children under 2 years of age unless under the advice and supervision of a physician.

**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.

**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.

**If pregnant or breast-feeding**, ask a health professional before use.

**Keep this and all drugs** out of reach of children. In case of ingestion, get medical help or contact a poison control center immediately.

#### **Directions**

- adults and children 2 years and older - apply to affected area not more than 3 or 4 times daily
- children under 2 years - consult a physician

#### **Other information**

- store at 59°-86° F (15°-30° C) in a dry place
- mfd. in the USA for B.F. Ascher & Co., Inc.

**Inactive ingredients:** aloe barbadensis leaf juice (aloe vera gel), blue 1, butylene glycol,

carbomer, citric acid, diazolidinyl urea, iodopropynyl butylcarbamate, potassium sorbate, SD alcohol 40, sodium benzoate, sodium sulfite, styrene/acrylates copolymer, tetrahydroxypropyl ethylenediamine, and water

**Questions?** Call 1-800-324-1880, 7:30am - 4:00pm Central, M - F, or visit [bfascher.com](http://bfascher.com)

Itch-X Gel PDP

The image shows the packaging for Itch-X Fast-Acting, Anti-Itch Gel. The top section is red with a green starburst on the left that says "35¢ OFF next Itch-X purchase COUPON INSIDE". To the right of the starburst, it says "Dermatologist Recommended" and "NDC 0225-0495-33". Below the starburst, the text "FAST ITCHING RELIEF!" is written in large, bold, black and red letters. To the right of this text is a list of conditions: "- Rashes", "- Allergic Itches", "- Minor Skin Irritation", "- Dry Skin Itch", "- Hives", "- Minor Burns", "- Insect Bites", and "- Poison Ivy, Oak, Sumac". Below this list, the text "Fast, long-acting relief of pain and itching associated with:" is written. The middle section of the packaging is yellow with the brand name "ITCH-X" in large, bold, black letters. Below this, the text "FAST-ACTING, ANTI-ITCH GEL" is written in bold, black letters. At the bottom, there is a red banner with a green leaf logo on the left, the text "with soothing ALOE VERA" in green, and "NET WT 35.4 g (1.25 OZ)" in white.

## ITCH X

benzyl alcohol/pramoxine hydrochloride gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0225-0495
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
-----------------	-------------------	----------

<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH) (BENZYL ALCOHOL - UNII:LKG8494WBH)	BENZYL ALCOHOL	10 g in 100 g
<b>PRAMOXINE HYDROCHLORIDE</b> (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>ALOE</b> (UNII: V5VD430YW9)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>EDETOL</b> (UNII: Q4R969U9FR)	
<b>CARBOMER HOMOPOLYMER TYPE B (ALLYL SUCROSE CROSSLINKED)</b> (UNII: Z135WT9208)	
<b>DIAZOLIDINYL UREA</b> (UNII: H5RIZ3MPW4)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SODIUM SULFITE</b> (UNII: VTK01UQK3G)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>IODOPROPYNYL BUTYLCARBAMATE</b> (UNII: 603P14DHEB)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>STYRENE/AMMONIUM ACRYLATE COPOLYMER (300000 MW)</b> (UNII: PA4J9TF5U2)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0225-0495-33	35.4 g in 1 TUBE; Type 0: Not a Combination Product	09/19/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	09/19/2014	

Labeler - BF ASCHER AND CO INC (003854403)