ITCH-X- pramoxine hcl/benzyl alcohol spray
BF ASCHER AND CO 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.

Itch-X Spray

Active ingredients..... Purpose
(in solution)
Benzyl alcohol 10%.....Topical analgesic
Pramoxine HCl 1%.....Topical analgesic

Uses temporarily relieves pain and itching associ- ated with insect bites, minor burns, sunburn, minor cuts, scrapes, minor skin irritations, hives and rashes due to poison ivy, poison oak, or poison sumac.

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Warnings

For external use only.
Avoid contact with eyes.
Keep away from fire or flame.

If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use and consult a physician.

Do not apply to open wounds, damaged, or blistered skin.

Do not use for vaginal, genital, or rectal itching.

Do not use on children under 2 years of age unless under the advice and supervision of a physician.

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

Keep this and all drugs out of reach of children. In case of overdose or ingestion of contents, 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)
- mfd. in the USA for B.F. Ascher & Co., Inc.

Inactive ingredients aloe barbadensis (aloe vera gel), SD alcohol 40, and water

Questions?

1-800-324-1880, 7:30am - 4:00pm Central, Mon. - Fri., or visit www.bfascher.com

Itch-X Spray PDP

ITCH-X

pramoxine hcl/benzyl alcohol spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0225-0516
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	1 g in 100 mL
BENZYL ALCOHOL (UNII: LKG8494WBH) (BENZYL ALCOHOL - UNII:LKG8494WBH)	BENZYL ALCOHOL	10 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALOE (UNII: V5VD430YW9)	
ALCOHOL (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0225-0516-51	59.1 mL in 1 BOTTLE, SPRAY; 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 not final	part348	09/19/2014	10/31/2025

Labeler - BF ASCHER AND CO INC (003854403)

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