

**CVS FRAGRANCE FREE ANTI-ITCH - pramoxine hydrochloride lotion**  
**RITE AID CORPORATION**

*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.*

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**DRUG FACTS**

**Active ingredient**

**Purpose**

Pramoxine Hydrochloride 1%.....External Analgesic

**Uses**

For the temporary relief of itching associated with minor skin irritations

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

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For the temporary relief of itching associated with minor skin irritations

**Warnings**

**For external use only**

**When using this product**

- avoid contact with eyes

**Stop use and ask a doctor if**

- condition worsens
- symptoms persist for more than 7 days or clear up and occur again within a few days.

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

**adults and children 2 years and older**

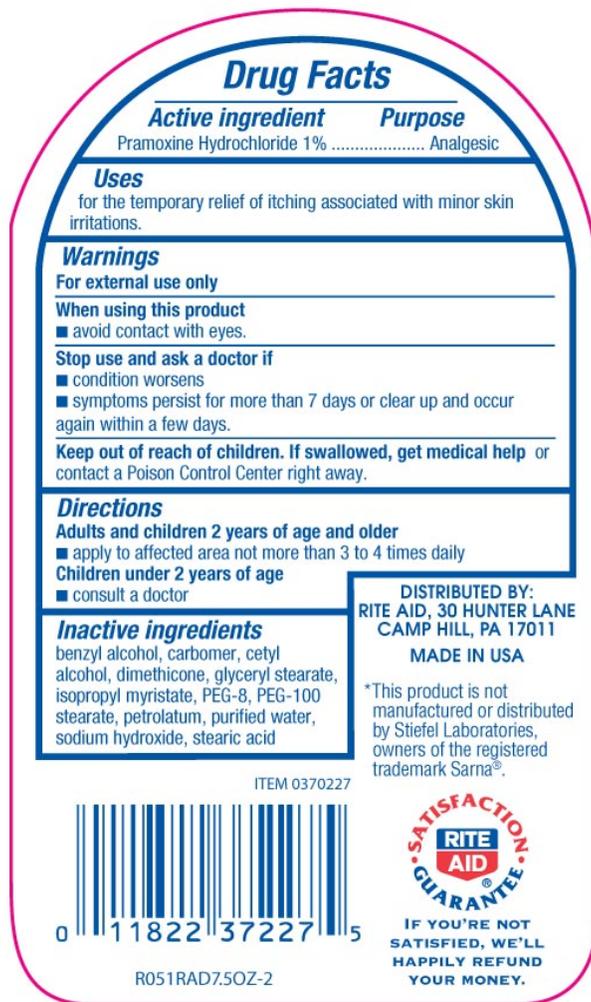
- apply to affected area not more than 3 to 4 times daily

**children under 2 years of age**

- consult a doctor

### Inactive Ingredients

benzyl alcohol, carbomer, cetyl alcohol, dimethicone, glycerul stearate, isopropyl myristate, PEG-8, PEG-100 stearate, petrolatum, purified water, sodium hydroxide, stearic acid



### CVS FRAGRANCE FREE ANTI-ITCH

pramoxine hydrochloride lotion

#### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:11822-0405
<b>Route of Administration</b>	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
PRAMO XINE HYDRO CHLORIDE (UNII: 88AYB867L5) (PRAMO XINE - UNII:068X84E056)	PRAMO XINE HYDROCHLORIDE	10 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CARBOMER HOMO POLYMER TYPE C (UNII: 4Q93RCW27E)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
PETROLATUM (UNII: 4T6H12BN9U)	
DIMETHICONE 350 (UNII: 2Y53S6ATLU)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
SODIUM HYDRO XIDE (UNII: 55X04QC32I)	
POLYETHYLENE GLYCOL 4500 (UNII: TVH7653921)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-0405-9	222 mL in 1 BOTTLE, PUMP		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/08/2010	

**Labeler** - RITE AID CORPORATION (014578892)

**Registrant** - Pharma Pac, LLC (140807475)

Establishment			
Name	Address	ID/FEI	Business Operations
Pharma Pac, LLC		140807475	manufacture