

**CVS FRAGRANCE FREE ANTI-ITCH - pramoxine hydrochloride lotion**

**CVS Pharmacy**

*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.....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

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



Compare to  
Sarna® Sensitive  
Anti-Itch Lotion\*

**Fragrance Free  
ANTI-ITCH  
LOTION  
SENSITIVE SKIN**

PRAMOXINE HYDROCHLORIDE 1%

- **Reduces & relieves itching associated with eczema, dry & sensitive skin**
- **Steroid free**



2.7 FL OZ (80mL)

<b>Drug Facts</b>	
<b>Active ingredient</b>	<b>Purpose</b>
Pramoxine hydrochloride 1% .....	External Analgesic
<b>Uses</b>	
for the temporary relief of itching associated with minor skin irritations	
<b>Warnings</b>	
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.	
<b>Directions</b>	
Adult and children 2 years of age and older	
■ apply to affected area not more than 3 to 4 times daily	
Children under 2 years of age	
■ consult a doctor	
<b>Inactive ingredients</b> purified water, isopropyl myristate, stearic acid, glyceryl stearate, PEG-100 stearate, cetyl alcohol, PEG-8, petrolatum, dimethicone, benzyl alcohol, carbomer, sodium hydroxide	

\* This product is not manufactured or distributed by Stiefel Laboratories, Inc., owner of the registered trademark Sarna®

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Money Back Guarantee

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### CVS FRAGRANCE FREE ANTI-ITCH

pramoxine hydrochloride lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59779-052
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE 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 HYDROXIDE (UNII: 55X04QC32I)	
POLYETHYLENE GLYCOL 4500 (UNII: TVH7653921)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-052-58	80 mL in 1 BOTTLE, PUMP		
2	NDC:59779-052-59	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** - CVS Pharmacy (062312574)

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

### Establishment

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