

**CVS MEDICATED ANTI-ITCH - menthol, pramoxine hydrochloride cream**

**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**

Menthol 1%.....Anti-Itch Pain Relief  
Pramoxine Hydrochloride 1%.....Anti-Itch Pain Relief

**Uses**

For the temporary relief of pain and discomfort cause by  
- minor burns - sunburn - scrapes - insect bites  
- minor skin irritations - rashes due to poison ivy, oak and sumac

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

**Uses**

For the temporary relief of pain and discomfort cause by  
- minor burns - sunburn - scrapes - insect bites  
- minor skin irritations - rashes due to poison ivy, oak and sumac

**Warnings**

**For external use only**

**Do Not use** - under bandages or compresses

**When using this product**

- avoid contact with the eyes

**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.

**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 2 tim

- **Children under 2 years of age:** do not use, consult a doctor

## **Inactive Ingredients**

Water, Propylene Glycol, Petrolatum, Stearyl Alcohol, Aloe Barbadensis Gel, Sodium Acrylates Copolymer, Mineral Oil, Steareth 21, PPG 1 Trideceth, 6, Toco[heryl Acetate, Disodium EDTA, Methyl Salicylate, Thymol, Eucalyptol, Triethanolamine, Iodopropynyl Butylcarbamate, Diozolidinyl Urea

**CVS**  
pharmacy

Enriched With Aloe & Vitamin E

**MAXIMUM STRENGTH**  
Relieves Pain & Itch Fast!

- Minor Skin Irritations, Cuts & Burns
- Dry Skin • Poison Ivy, Oak & Sumac
- Insect Bites • Scrapes • Sunburn

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Compare to the active ingredient in Gold Bond®\*



**Medicated ANTI-ITCH CREAM**  
**MAXIMUM STRENGTH**

The maximum pain & itch relief you can get without a prescription

NET WT 2 OZ (56 g)

**Medicated ANTI-ITCH CREAM**  
**MAXIMUM STRENGTH**



www.cvs.com

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Woonsocket, RI 02895

Distributed by: CVS Pharmacy, Inc.

\* This product is not manufactured or distributed by Chatterm, Inc., owner of the brand name Gold Bond®

<b>Drug Facts</b>
<b>Active ingredient</b> Menthol 1%, Pramoxine Hydrochloride, 1%, Anti-Itch, Pain Relief
<b>Uses</b> For the temporary relief of pain and discomfort caused by • minor skin irritations • rashes due to poison ivy, oak & sumac • insect bites
<b>Warnings</b> • For external use only Do not use • under bandages or compresses
<b>When using this product</b> • Avoid contact with the eyes
<b>Stop use and ask a doctor</b> • If condition worsens, or if symptoms persist for more than 7 days, or clear up and occur again within a few days
<b>Directions</b> Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
• Adults and children 2 years of age and older: apply to the affected area no more than 2 times daily
• Children under 2 years of age: do not use, consult a doctor
<b>Inactive ingredients</b> Copolymer, Mineral Oil, Steareth 21, PEG 1 Trideceth 6, Tocopheryl Acetate, Disodium EDTA, Methyl Salicylate, Thymol, Eucalyptol, Triethanolamine, Iodopropylmyl Butylcarbamate, Diazolidinyl Urea
<b>Other information</b> Distributed by: CVS Pharmacy, Inc.

**Medicated ANTI-ITCH CREAM**  
**MAXIMUM STRENGTH**

**LOT NO.**  
**EXP.**

**CVS MEDICATED ANTI-ITCH**  
menthol, pramoxine hydrochloride cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59779-621	
<b>Route of Administration</b>	TOPICAL			
<b>Active Ingredient/Active Moiety</b>				
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>	
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)		PRAMOXINE HYDROCHLORIDE	10 mg in 1 g	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)		MENTHOL	10 mg in 1 g	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>			<b>Strength</b>	
WATER (UNII: 059QF0KO0R)				
STEARYL ALCOHOL (UNII: 2KR89I4HIY)				
PETROLATUM (UNII: 4T6H12BN9U)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
TRIDECETH-6 (UNII: 3T5PCR2H0C)				
STEARETH-21 (UNII: 53J3F32P58)				
STEARETH-2 (UNII: V56DFE46J5)				
THYMOL (UNII: 3J50XA376E)				
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)				
METHYL SALICYLATE (UNII: LAV5U5022Y)				
EDETATE DISODIUM (UNII: 7FLD91C86K)				
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)				
TROLAMINE (UNII: 9O3K93S3TK)				
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
EUCALYPTUS OIL (UNII: 2R04ONI662)				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:59779-621-64	1 in 1 CARTON		
1		56 g in 1 TUBE		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
OTC monograph final	part347	07/08/2010		

**Labeler** - CVS Pharmacy (062312574)

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

## Establishment

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

Revised: 7/2010

CVS Pharmacy