

**ARTHRITIS PAIN RELIEF- histamine dihydrochloride cream**  
**PainX LLC**

*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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**PAINX - ARTHRITIS PAIN RELIEF (83041-101)**

**ACTIVE INGREDIENT**

HISTAMINE DIHYDROCHLORIDE 0.03%

**PURPOSE**

TOPICAL ANALGESIC

**USES**

For the temporary relief of minor aches and pains of muscles and joints associated with arthritis, simple backache, strains and bruises.

**WARNINGS**

For external use only.

Do not use on wounds or damaged skin or if you are allergic to ingredients in the product.

When using this product avoid contact with eyes. If product gets into eyes, rinse thoroughly with water.

Do not bandage tightly or use a heating pad.

Stop using and ask doctor if

- Rash appears.
- Condition worsens, if symptoms persists for more than 7 days, or if symptoms clear up and occur again within a few days.

**DIRECTIONS**

- For use by Adults and children over 12 years.
- Apply a thin layer to pain site and massage until thoroughly absorbed into skin. Apply no more than 3 to 4 times daily.
- Children 12 years or younger consult a physician.

IF PREGNANT OR BREAST FEEDING, ASK A HEALTH PROFESSIONAL BEFORE USE.

KEEP OUT OF REACH OF CHILDREN. IF SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTRE RIGHT AWAY.

## OTHER INFORMATION

- Store between 40°F and 86°F (4°C and 30°C)
- Tamper Evident Feature: do not use if seal under cap is torn, broken or missing.

## INACTIVE INGREDIENTS

Water, Cetearyl Alcohol, Dimethicone, Caprylic/Capric Triglyceride, Stearyl Alcohol, Glycerin, Methylsulfonylmethane, Glyceryl Stearate, PEG-100 Stearate, Simmondsia Chinensis (Jojoba) Seed Oil, Carthamus Tinctorius (Safflower) Seed Oil, Emu Oil, Stearic Acid, Tocopheryl (Vitamin E) Acetate, Glucosamine Hydrochloride, Phenoxyethanol, Menthol, Carbomer, Curcuma Longa (Turmeric) Root Extract, Chamomilla Recutita (Matricaria) Flower Extract, Aloe Barbadensis Leaf Juice, Triethanolamine, Ethylhexylglycerin, Disodium EDTA.

<p><b>DIRECTIONS</b></p> <ul style="list-style-type: none"> <li>■ For use by Adults and children over 12 years.</li> <li>■ Apply a thin layer to pain site and massage until thoroughly absorbed into skin. Apply no more than 3 to 4 times daily.</li> <li>■ Children 12 years or younger consult a physician.</li> </ul> <p><b>OTHER INFORMATION</b></p> <ul style="list-style-type: none"> <li>■ Store between 40oF and 86oF (4oC and 30oC)</li> <li>■ Tamper Evident Feature: do not use if seal under cap is torn, broken or missing.</li> </ul> <p><b>INACTIVE INGREDIENTS</b></p> <p>Water, Cetearyl Alcohol, Dimethicone, Caprylic/Capric Triglyceride, Stearyl Alcohol, Glycerin, Methylsulfonylmethane, Glyceryl Stearate, PEG-100 Stearate, Simmondsia Chinensis (Jojoba) Seed Oil, Carthamus Tinctorius (Safflower) Seed Oil, Emu Oil, Stearic Acid, Tocopheryl (Vitamin E) Acetate, Glucosamine Hydrochloride, Phenoxyethanol, Menthol, Carbomer, Curcuma Longa (Turmeric) Root Extract, Chamomilla Recutita (Matricaria) Flower extract, Aloe Barbadensis Leaf Juice, Triethanolamine, Ethylhexylglycerin, Disodium EDTA.</p>	<p><b>Stop the pain It's that simple.</b> We developed PainX in order to offer the highest quality, USA made products that just work. You don't have the time or money to waste on things that don't deliver results. PainX arthritis pain relief cream is for the temporary relief of minor aches and pains in the joints and muscles associated with arthritis.</p> <p>PainX delivers deep, penetrating relief to the affected areas so that you can get on with your busy, active life. We are so confident in our products that we offer a 100%, no questions asked guarantee. If you are not completely satisfied, mail the original receipt to 1878 Horse Creek Rd., Cheyenne, WY 82009. Please allow 6-weeks for processing. Limit one refund per customer.</p> <p><b>IF PREGNANT OR BREAST FEEDING, ASK A HEALTH PROFESSIONAL BEFORE USE.</b></p> <p><b>KEEP OUT OF REACH OF CHILDREN. IF SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTRE RIGHT AWAY.</b></p>	<p><b>DRUG FACTS</b></p> <p><b>ACTIVE INGREDIENT:</b> Histamine Dihydrochloride.....0.03%</p> <p><b>PURPOSE:</b> Topical Analgesic</p> <p><b>USES:</b> For the temporary relief of minor aches and pains of muscles and joints associated with arthritis, simple backache, strains and bruises.</p> <p><b>WARNINGS:</b> For external use only. <b>Do not use</b> on wounds or damaged skin or if you are allergic to ingredients in the product. <b>When using this product</b> avoid contact with eyes. If product gets into eyes, rinse thoroughly with water. Do not bandage tightly or use a heating pad.</p> <p><b>Stop using and ask doctor if</b></p> <ul style="list-style-type: none"> <li>■ Rash appears.</li> <li>■ Condition worsens, if symptoms persists for more than 7 days, or if symptoms clear up and occur again within a few days.</li> </ul>	<p>STOP THE PAIN</p> <p><b>PAINX</b></p> <p>MADE IN USA</p>	<p><b>#1 DOCTOR RECOMMENDED</b></p> <p><b>ARTHRITIS PAIN RELIEF</b></p> <p>FAST-ACTING LONG-LASTING</p> <p><b>GUARANTEED PAIN RELIEF</b></p> <p>ACTIVE INGREDIENT HISTAMINE DIHYDROCHLORIDE</p> <p>4OZ (119g)</p>
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## ARTHRITIS PAIN RELIEF

histamine dihydrochloride cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:83041-101
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>HISTAMINE DIHYDROCHLORIDE</b> (UNII: 3POA0Q644U) (HISTAMINE - UNII:820484N8I3)	HISTAMINE DIHYDROCHLORIDE	0.03 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>MATRICARIA CHAMOMILLA FLOWERING TOP</b> (UNII: 3VNC7T6Z02)	
<b>JOJOBA OIL</b> (UNII: 724GKU717M)	

<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)
<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)
<b>GLUCOSAMINE HYDROCHLORIDE</b> (UNII: 750W5330FY)
<b>MENTHOL</b> (UNII: L7T10EIP3A)
<b>CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE</b> (UNII: 0A5MM307FC)
<b>TURMERIC</b> (UNII: 856YO1Z64F)
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)
<b>SAFFLOWER OIL</b> (UNII: 65UEH262IS)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>WATER</b> (UNII: 059QF0KO0R)
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)
<b>DIMETHYL SULFONE</b> (UNII: 9H4PO4Z4FT)
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)
<b>EMU OIL</b> (UNII: 344821WD61)
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83041-101-14	119 g in 1 JAR; Type 0: Not a Combination Product	11/07/2022	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	11/07/2022	

**Labeler** - PainX LLC (118688116)

**Registrant** - PainX LLC (118688116)