

**PAIN RELIEVING ROLL-ON- menthol, camphor, capsaicin lotion**  
**AHC VENTURES CORP DBA CRY**

*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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**Cryoderm Heat Warming Roll On**

**Warnings:**

**For external use only**

**Purpose**

Pain Reliever

**Other Information**

Store in a cool dry place with lid or cap closed tightly.

Flammable: Keep away from excessive heat or open flame

**Active Ingredient**

Menthol USP 3.85%

Camphor USP 3.85%

Capsaicin USP 0.0355%

**Directions**

**Adults and children 2 years and older:**

Apply a small amount directly on the skin over the affected area without the need to rub, massage or bandage. Repeat as necessary but do not apply more than 4 times daily.

**Children under 2 years of age:** Consult a Physician

**Keep Out of Reach of Children**

In case of accidental ingestion get medical help or contact a Poison Control Center immediately

**Inactive Ingredients**

Aloe Vera, Arnica Extract, Boswellia Serrata Extract, Green Tea Extract, Carbomer, Cetearyl Alcohol, Cetearyl Glucoside, Orange Fruit Extract, Grapefruit Extract, Dimethyl Sulfone, Ethylhexylglycerin, Glycerin, Ilex Paraguariensis Leaf Extract, Phenoxyethanol,

Purified Water, Rose Extract, Vitamin E, Triethanolamine, Yucca Extract

## **Uses**

Temporary relieves minor aches and pains associated with

- sore muscles and joints
- arthritis
- backache
- muscle strains
- sprains
- bruises

## **When using this product:**

Use only as directed. Do not bandage or use a heating pad or device. Avoid contact with eyes and mucous membranes. Do not apply to open wounds or damaged skin. Do not use with other ointment, creams, sprays or liniments. After applying wash hands thoroughly with cool water

## **Stop use and ask a doctor if:**

Condition worsens or symptoms persist for more than 7 days or clear up and recur. Redness is present or irritatio develops

## **If Pregnant or Breast Feeding:**

Ask a health professional before use

## **This product contains Capsaicin**

and may cause temporary burning, stinging, inflammation, redness or welts on the application site that usually disappear in a few days. If you experience any of these symptoms discontinue use and contact your doctor immediately

## **PDP**

CryoDerm

HEAT

PAIN RELIEVING

WARMING Therapy

ROLL-ON

Fast, Deep Penetrating Pain Relief for:

Muscle Strains, Joint Pain, Backache, Arthritis, Sprained Ligaments & Bruises

Paraben Free / Propylene Glycol Free / Aspirin Free  
NSAID Free / Silicone Dioxide Free / Gluten Free

Contains Essential Oils & Natural Extracts

MSM Arnica Boswellia Ilex

Active Ingredients:  
Menthol . Camphor . Capsaicin

3 fl.oz. 84mL



# HEAT

## Pain Relieving Warm Therapy

**ROLL-ON**

Fast Acting, Penetrating Pain Relief For:  
Muscle Strains, Joint Pain, Backache,  
Arthritis, Sprained Ligaments & Bruises.

Paraben Free / Propylene Glycol Free / Aspirin Free  
NSAID Free / Silicon Dioxide Free / Gluten Free

Contains Essential Oils and Natural Extracts  
**MSM • Arnica • Boswellia • Ilex**

Active Ingredients:  
Menthol • Camphor • Capsaicin

3 fl. oz. • 84mL

Drug Facts	
<b>Active Ingredient</b>	<b>Purpose</b>
Menthol USP 3.85% .....	Pain Reliever
Camphor USP 3.85% .....	Pain Reliever
Capsaicin USP 0.0355% .....	Pain Reliever
<b>Uses:</b> Temporarily relieves minor aches and pains associated with • sore muscles and joints • arthritis • backache • muscle strains • sprains • bruises	
<b>Warnings:</b> For external use only	
<b>This product contains Capsaicin</b> and may cause temporary burning, stinging, inflammation, redness or welts on the application site that usually disappear in a few days. If you experience any of these symptoms discontinue use and contact a health care provider immediately	
<b>When using this product:</b> Use only as directed • Do not bandage or cover the area being treated • Do not apply ice or heating pad in conjunction with this product • Do not use with any medical device or other device • Do not combine with any other topical treatments • Avoid contact with eyes or mucous membrane • Do not apply to wounds or damaged skin	
<b>Stop use and ask a doctor if:</b> Condition worsens or symptoms persist for more than 7 days or clear up and recur • Redness is present or irritation develops	
<b>If Pregnant or Breast Feeding:</b> Ask a healthcare professional before use	
<b>Keep Out of Reach of Children:</b> In case of accidental ingestion get medical help or contact a Poison Control Center Immediately	
<b>Directions - Adults and children 2 years of age and older:</b> Apply a small amount directly on the skin over the affected area without the need to rub, massage or bandage • Repeat as necessary but do not apply more than 4 times daily. <b>Children under 2 years of age:</b> Consult a Physician	
<b>Other Information:</b> Store in a cool dry place with lid or cap closed tightly <b>Flammable:</b> Keep away from excessive heat or open flame	
<b>Inactive Ingredients:</b> Aloe Vera, Arnica Extract, Boswellia Serrata Extract, Green Tea Extract, Carbomer, Cetearyl Alcohol, Cetearyl Glucoside, Orange Fruit Extract, Grapefruit Extract, Dimethyl Sulfone (MSM), Ethylhexylglycerine, Glycerin, Ilex Paraguariensis Leaf Extract, Phenoxethanol, Purified Water, Rose Extract, Vitamin E, Triethanolamine, Yucca Extract	

NDC # 68678-040-90

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Lot/Exp:

PAIN RELIEVING ROLL-ON			
menthol, camphor, capsaicin lotion			
Product Information			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68678-040
<b>Route of Administration</b>	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	3.85 g in 100 mL	

<b>CAMPHOR (SYNTHETIC)</b> (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	3.85 g in 100 mL
<b>CAPSAICIN</b> (UNII: S07O44R1Z M) (CAPSAICIN - UNII:S07O44R1Z M)	CAPSAICIN	0.0355 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0K00R)	77.3645 mL in 100 mL
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	0.5 mL in 100 mL
<b>ARNICA MONTANA</b> (UNII: O80TY208ZW)	0.5 mL in 100 mL
<b>BOSWELLIA SERRATA WHOLE</b> (UNII: X7B7P649WQ)	0.5 mL in 100 mL
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)	0.5 mL in 100 mL
<b>CARBOMER 940</b> (UNII: 4Q93RCW27E)	0.4 mL in 100 mL
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	1 mL in 100 mL
<b>CETEARYL GLUCOSIDE</b> (UNII: 09FUA47KNA)	1 mL in 100 mL
<b>CITRUS AURANTIUM FRUIT</b> (UNII: DQD16J2B5O)	0.5 mL in 100 mL
<b>GRAPEFRUIT</b> (UNII: O82C39RR8C)	0.5 mL in 100 mL
<b>DIMETHYL SULFONE</b> (UNII: 9H4PO4Z4FT)	3.5 mL in 100 mL
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	0.3 mL in 100 mL
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	3 mL in 100 mL
<b>ILEX PARAGUARIENSIS LEAF</b> (UNII: 1Q953B404F)	0.5 mL in 100 mL
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	0.7 mL in 100 mL
<b>ROSA CANINA FLOWER</b> (UNII: 81MCR2UQ6Q)	0.5 mL in 100 mL
<b>.ALPHA.-TOCOPHEROL ACETATE, D-</b> (UNII: A7E6112E4N)	0.5 mL in 100 mL
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	0.5 mL in 100 mL
<b>YUCCA SCHIDIGERA</b> (UNII: 08A0YG3VIC)	0.5 mL in 100 mL

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68678-040-90	84 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	01/01/2016	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/01/2016	

Revised: 4/2022

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