

PAIN RELIEVING- 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.

Cryoderm Heat Warming Lotion

Directions

Adults and children 2 years and older:

Massage a small amount of lotion directly on the skin over the affected area. Repeat as necessary but do not apply more than 4 times daily.

Children under 2 years of age: Consult a Physician

Active Ingredient

Menthol USP 3.85%

Camphor USP 3.85%

Capsaicin USP 0.0355%

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

Other Information

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

Flammable: Keep away from excessive heat or open flame

Keep Out of Reach of Children

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

Purpose

Pain Reliever

Uses

Temporary relieves minor aches and pains associated with

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

Warnings

For external use only

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 irritation 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

CryoDerm

HEAT

PAIN RELIEVING

WARM Therapy

Lotion

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

16 fl.oz. 449mL

CRYODERM®

HEAT Pain Relieving Warm Therapy

LOTION

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

Paraben Free / Propylene Glycol Free / Aspirin Free
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Contains Essential Oils and Natural Extracts

MSM • Arnica • Boswellia • Ilex

Active Ingredients:
Menthol • Camphor • Capsaicin

16 fl. oz. • 449mL

Drug Facts	
Active Ingredient	Purpose
Menthol USP 3.85%	Pain Reliever
Camphor USP 3.85%	Pain Reliever
Capsaicin USP 0.0355%	Pain Reliever
Uses: Temporarily relieves minor aches and pains associated with • sore muscles and joints • arthritis • backache • muscle strains • sprains • bruises	
Warnings: For external use only	
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 a health care provider immediately	
When using this product: 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	
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 irritation develops	
If Pregnant or Breast Feeding: Ask a healthcare professional before use	
Keep Out of Reach of Children: In case of accidental ingestion get medical help or contact a Poison Control Center immediately	
Directions - Adults and children 2 years of age and older: Massage a small amount of lotion directly on the skin over the affected area • Repeat as necessary but do not apply more than 4 times daily. Children under 2 years of age: Consult a Physician	
Other Information: Store in a cool dry place with lid or cap closed tightly Flammable: Keep away from excessive heat or open flame	
Inactive Ingredients: 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, Phenoxyethanol, Purified Water, Rose Extract, Vitamin E, Triethanolamine, Yucca Extract	

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NDC # 68678-039-16



Lot/Exp:

PAIN RELIEVING

menthol, camphor, capsaicin lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68678-039
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength

MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	3.85 g in 100 mL
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	3.85 g in 100 mL
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.0355 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	77.3645 mL in 100 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.5 mL in 100 mL
ARNICA MONTANA (UNII: O80TY208ZW)	0.5 mL in 100 mL
BOSWELLIA SERRATA WHOLE (UNII: X7B7P649WQ)	0.5 mL in 100 mL
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	0.5 mL in 100 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	0.4 mL in 100 mL
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	1 mL in 100 mL
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	1 mL in 100 mL
CITRUS AURANTIUM FRUIT (UNII: DQD16J2B5O)	0.5 mL in 100 mL
GRAPEFRUIT (UNII: O82C39RR8C)	0.5 mL in 100 mL
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	3.5 mL in 100 mL
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	0.3 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	3 mL in 100 mL
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	0.5 mL in 100 mL
PHENOXYETHANOL (UNII: HIE492ZZ3T)	0.7 mL in 100 mL
ROSA CANINA FLOWER (UNII: 81MCR2UQ6Q)	0.5 mL in 100 mL
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	0.5 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.5 mL in 100 mL
YUCCA SCHIDIGERA (UNII: 08A0YG3VIC)	0.5 mL in 100 mL

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68678-039-16	449 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	01/01/2016	
2	NDC:68678-039-04	112 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	01/01/2016	
3	NDC:68678-039-99	3.35 mL in 1 PACKET; Type 0: Not a Combination Product	01/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC monograph not final	part348	01/01/2016	
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Labeler - AHC VENTURES CORP DBA CRY (131871779)

Revised: 5/2022

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