

COLD THERAPY- menthol gel
AHC VENTURES CORP DBA CRYODERM

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.

Active Ingredient

Menthol USP 10.0%

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 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

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 and older:

Apply directly onto 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

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:

Acrylates, Arnica, Boswellia Serrata, Eucalyptus Oil, Glycerin, Ilex Paraguariensis Leaf Extract, Dimethyl Sulfone, Peppermint Oil, Purified Water, SD Alcohol 39-C, Triethanolamine

PDP

CryoDerm

Pain Relieving Cold Therapy

Gel

Fast Acting, Penetrating Pain Relief For:

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

Contains Essential Oils and Natural Extracts

MSM Arnica Boswellia Ilex

Active Ingredient: Menthol

4 fl. oz. 126mL

CRYODERM®

Pain Relieving Cold Therapy

GEL

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

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

Active Ingredient: Menthol

4 fl. oz. • 126mL

Drug Facts

Active Ingredient	Purpose
Menthol USP 10.0%.....	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

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 liberal amount of gel 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: Acrylates, Arnica, Boswellia Serrata, Eucalyptus Oil, Glycerin, Ilex Paraguariensis Leaf Extract, Dimethyl Sulfone (MSM), Peppermint Oil, Purified Water, SD Alcohol 39-C, Triethanolamine

NDC # 68678-011-05



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Lot/Exp:



COLD THERAPY

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68678-011
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ARNICA MONTANA (UNII: O80TY208ZW)	1 mL in 100 mL
BOSWELLIA SERRATA WHOLE (UNII: X7B7P649WQ)	1 mL in 100 mL
EUCALYPTOL (UNII: RV6J6604TK)	0.05 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	5 mL in 100 mL
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B404F)	1 mL in 100 mL

DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	0.03 mL in 100 mL
PEPPERMINT OIL (UNII: AV092KU4JH)	0.05 mL in 100 mL
WATER (UNII: 059QF0KO0R)	32.906 mL in 100 mL
ALCOHOL (UNII: 3K9958V90M)	48.4 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.5 mL in 100 mL
(C10-C30)ALKYL METHACRYLATE ESTER (UNII: XH2FQZ38D8)	0.004 mL in 100 mL

Product Characteristics

Color	yellow	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68678-011-05	126 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	01/01/2016	
2	NDC:68678-011-17	504 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	01/01/2016	
3	NDC:68678-011-99	3 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
OTC monograph not final	part348	01/01/2016	

Labeler - AHC VENTURES CORP DBA CRYODERM (131871779)

Revised: 4/2022

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