CRYOFREEZE ROLL-ON REGULAR STRENGTH- menthol, unspecified form gel
Omax Health, Inc

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.

Cryofreeze™ Roll-On Regular Strength

Drug Facts

Active Ingredients

Natural Menthol, USP (8.5%)

Purpose

Topical Analgesic

Uses

Temporary relief from minor aches and pains from sore muscles and joints, backache, arthritis.

Warnings

For external use only.

Flammable: Keep out of reach of children.

Contact a doctor before using if have sensitive skin or are pregnant, breastfeeding or on any medications. If swallowed get medical help or call Poison control center immediately.

Directions

Use only as directed. Do not use on children under 12 years of age. Roll onto affected area no more than four times daily.

When using this product

Do not use with heating pad. Do not bandage. Wash hands with cold water immediately after use and do not touch eyes or mucous membranes. **Stop use and ask a doctor** if redness or irritation occurs, if condition worsens, or if pain persists for more than 7 days or clears up, then reoccurs.

Inactive Ingredients

Aloe Barbadensis Leaf Extract, Arnica Montana Flower Extract, Boswellia Serrata

Extract, Camphor, Industrial Hemp Extract, Carbomer, Chondroitin Sulfate, Ethylhexylglycerin, Glucosamine Sulfate, Glycerin, Ilex Paraguariensis Extract, Isopropyl Alcohol, Methyl Sulfonylmethane, Peppermint Oil, Phenoxyethanol, Polysorbate 20, Propylene Glycol, Purified Water, Triethanolamine. **No Parabens.**

Other Information

Questions call 1-800-765-6691. Store in a cool dry place with the cap tightly closed. Note: Because this product contains natural ingredients, colors may vary.

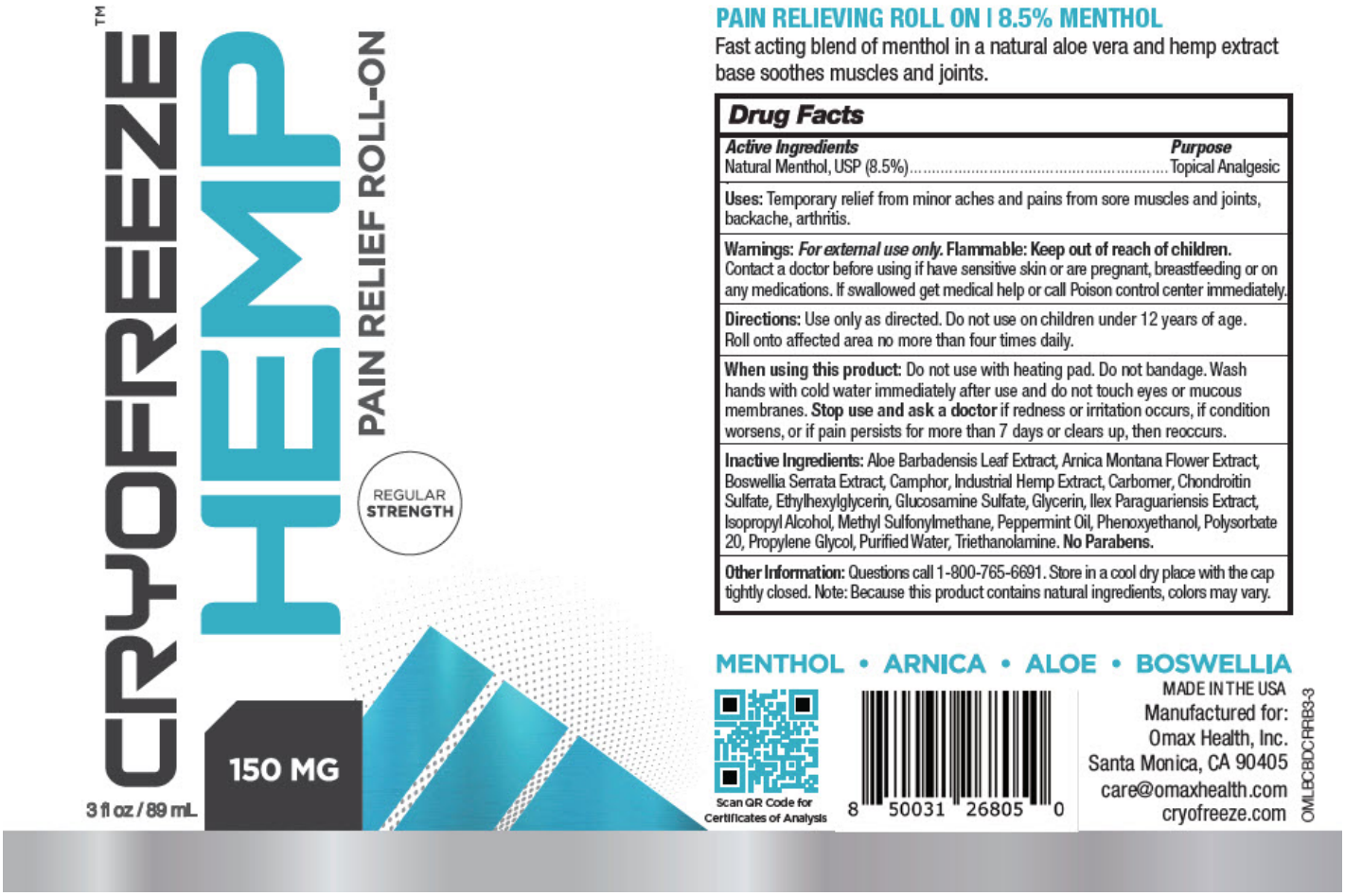
PRINCIPAL DISPLAY PANEL - 89 mL Bottle Label

CRYOFREEZE™
HEMP
PAIN RELIEF ROLL-ON

REGULAR
STRENGTH

3 fl oz / 89 mL

150 MG



CRYOFREEZE ROLL-ON REGULAR STRENGTH

menthol, unspecified form gel

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:73036-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	85 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ARNICA MONTANA WHOLE (UNII: O80TY208ZW)	
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
HEMP (UNII: TD1MUT01Q7)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
CHONDROITIN SULFATE (SHARK) (UNII: 2ZAJ1K50XH)	
GLUCOSAMINE SULFATE POTASSIUM CHLORIDE (UNII: 15VQ11I66N)	
GLYCERIN (UNII: PDC6A3C0OX)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73036-003-01	89 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	03/16/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not			

OTC monograph not final	part348	03/16/2022	

Labeler - Omax Health, Inc (965730778)

Revised: 3/2022 Omax Health, Inc