

CRYODERM®



PAIN RELIEVING COLD THERAPY SPRAY

Vanishing Scent • Natural Soothing Menthol
Essential Oils & Natural Extracts

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

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

Pain Relieving Liquid • Greaseless • No-Mess • Non-Staining

4 fl. oz. • 126mL

Drug Facts

Active Ingredient Menthol USP 10.0%	Purpose 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 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 ointments, 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	
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: Spray 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: Arnica, Boswellia Serrata, Eucalyptus Oil, Ilex Paraguariensis Leaf Extract, Dimethyl Sulfone (MSM), Peppermint Oil, Purified Water, SD Alcohol 39-C.	

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MADE IN THE U.S.A.



NDC # 68678-011-04

COLD THERAPY

menthol spray

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 FLOWER (UNII: OZ0E5Y15PZ)	1 mL in 100 mL
BOSWELLIA SERRATA WHOLE (UNII: X7B7P649WQ)	1 mL in 100 mL
EUCALYPTOL (UNII: RV6J6604TK)	0.05 mL in 100 mL
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B404F)	1 mL in 100 mL
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	2 mL in 100 mL
PEPPERMINT OIL (UNII: AV092KU4JH)	0.05 in 100 mL

WATER (UNII: 059QF0KO0R)	33.5 in 100 mL
ALCOHOL (UNII: 3K9958V90M)	51.4 mg 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:68678-011-32	1008 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		
2	NDC:68678-011-16	504 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		
3	NDC:68678-011-04	126 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		

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)

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