PROTEC PAIN RELIEF COLD THERAPY- menthol spray AHC VENTURES

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 8.0%

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 pd 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, 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 accidential 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 the 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

Ilex Paraguariensis Leaf Extract, Arnica, Boswellia Serrata, Eucalyptus Oil, Peppermint Oil, Hyaluronic Acid, Yucca Extract, Nitric Oxide, Dimethyl Sulfone, Citric Acid, SD Alcohol 39 C, Purified Water

PRO-TEC ATHLETICS
PAIN RELIEF
ALL NATURAL SPRAY
RECOVERY COLD THERAPY
Fast Acting, Deep Penetrating Pain Relief from: Muscle Strains, Joint Pain, Tendinitis, Arthritis, Sprained Ligaments & Bruises
4 fl.oz./126 mL



PROTEC PAIN RELIEF COLD THERAPY

menthol spray

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68678-065
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	8 g in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
ALCOHOL (UNII: 3K9958V90M)	51.079 mL in 100 mL		
EUCALYPTUS OIL (UNII: 2R04ONI662)	.05 mL in 100 mL		
PEPPERMINT OIL (UNII: AV092KU4JH)	.05 mL in 100 mL		
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	5.0 mL in 100 mL		
HYALURO NIC ACID (UNII: S270 N0 TRQY)	.001 mL in 100 mL		
ARNICA MONTANA (UNII: O80TY208ZW)	1.00 mL in 100 mL		
BOSWELLIA SERRATA WHOLE (UNII: X7B7P649WQ)	1.00 mL in 100 mL		
YUCCA SCHIDIGERA (UNII: 08 A0 YG3VIC)	.1 mL in 100 mL		
DIMETHYL SULFONE (UNII: 9 H4PO4Z4FT)	3.0 mL in 100 mL		
WATER (UNII: 059QF0KO0R)	30.699 mL in 100 mL		
NITRIC O XIDE (UNII: 31C4KY9ESH)	.001 mL in 100 mL		
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)	.001 mL in 100 mL		

Product Characteristics			
Color	ye llo w	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

ı	Pa	ckaging			
	#	Item Code	em Code Package Description		Marketing End Date
	1 N		126 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	0 2/24/20 16	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	0 2/24/20 16	

Labeler - AHC VENTURES (131871779)

Establishment				
Name	Address	ID/FEI	Business Operations	
AHC VENTURES		131871779	manufacture(68678-065)	

Revised: 2/2016 AHC VENTURES