

PROTEC ROLL-ON- menthol gel
ACH VENTURES CORP

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 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, 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 of age and older: Roll 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 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, SD Alcohol 39 C, Purified Water, Glycerin, Acrylates, Triethanolamine

PRO.TEC ATHLETICS

PAIN RELIEF

ALL NATURAL ROLL ON

RECOVERY COLD THERAPY

Fast Acting, Deep Penetrating Pain Relief from: Muscle Strains, Joint Pain, Tendinitis, Arthritis, Sprained Ligaments & Bruises

3 fl.oz./95 mL

Drug Facts	
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Redmond, WA USA

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Manufactured for Pro-Tec Athletics by AHC Ventures, Corp.
NDC # 68678-067-03

PROTEC ROLL-ON

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68678-067
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)	50 mL in 100 mL
WATER (UNII: 059QF0K00R)	26.99 mL in 100 mL
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	5 mL in 100 mL
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	3 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	3 mL in 100 mL
BOSWELLIA SERRATA WHOLE (UNII: X7B7P649WQ)	1 mL in 100 mL
ARNICA MONTANA (UNII: O80TY208ZW)	1 mL in 100 mL
(C10-C30)ALKYL METHACRYLATE ESTER (UNII: XH2FQZ38D8)	.40 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	.40 mL in 100 mL
YUCCA SCHIDIGERA (UNII: 08A0YG3VIC)	.10 mL in 100 mL
PEPPERMINT OIL (UNII: AV092KU4JH)	.05 mL in 100 mL
EUCALYPTUS OIL (UNII: 2R04ONI662)	.05 mL in 100 mL
NITRIC OXIDE (UNII: 31C4KY9ESH)	.001 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:68678-067-04	95 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	02/19/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	02/19/2016	

Labeler - ACH VENTURES CORP (131871779)

Establishment

Name	Address	ID/FEI	Business Operations
ACH VENTURES CORP		131871779	manufacture(68678-067)

Revised: 2/2016

ACH VENTURES CORP