

**PROFESSIONAL THERAPY MUSCLECARE PAIN RELIEVING GEL EXTRA STRENGTH-
camphor, menthol gel**

Active and Innovative 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.

Professional Therapy MuscleCare pain relieving gel, 3 oz roll-on

Active Ingredients (% by weight) Purpose

Camphor 4.0%.....Analgesic (pain relief)

Menthol 10.0%.....Analgesic (pain relief)

Uses:

For temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises and sprains, etc.

Warnings:

For external use only.

- Caution: Discontinue use if excessive irritation of the skin develops. Avoid getting into eyes or on mucous membranes
- If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product and consult a doctor.
- Do not apply to wounds or damaged skin. Do not bandage tightly.

Keep out of reach of children.

- Use only as directed.
- Do not use if pregnant or breastfeeding.
- If swallowed, get medical help or contact a Poison Control center right away.

Directions:

Adults and children 12 years of age or older: Using the roll-on applicator massage a liberal amount of gel directly on the affected area not more than 3 to 4 times daily. Children under the age of 12: Do not use, consult a doctor.

Other Information:

Store under normal storage conditions. Store away from children.

Inactive Ingredients:

Alcohol Denat., Acrylates Copolymer, Water, Eucalyptus Globulus Leaf Oil, Mentha Piperita (Peppermint Oil), Propylene Glycol, Glycerin, MSM (Methylsulfonylmethane), Boswellia Serrata Extract, Ilex Paraguensis (Yerba Mate Ilex) Extract, Glucosamine Sulfate, Chondroitin Sulfate,

Magnesium Chloride, Triethanolamine.

FOR MUSCLE & JOINT PAIN RELIEF

Extra Strength Pain Relieving Gel

by Dr. Chris Oswald

Net Wt

3oz. (85g)

4.75"

<p>DRUG FACTS</p> <p>Active Ingredients (% by weight)</p> <p>Cannabinoid 4.0% Analgesic (pain relief)</p> <p>Menthol 10.0% Analgesic (pain relief)</p> <p>Uses: For the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises and sprains, etc.</p> <p>Warnings:</p> <p><i>For external use only.</i></p> <ul style="list-style-type: none"> Caution: Discontinue use if excessive irritation of the skin develops. Avoid getting into eyes or on mucous membranes. If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product and consult a doctor. Do not apply to wounds or damaged skin. Do not bandage tightly. <p>Keep out of reach of children.</p> <ul style="list-style-type: none"> Use only as directed. Do not use if pregnant or breastfeeding. If swallowed, get medical help or contact a Poison Control center right away. <p>Directions: Adults and children 12 years of age or older: Using the roll-on applicator massage a liberal amount of gel directly on the affected area not more than 3 to 4 times daily. Children under the age of 12: Do not use, consult a doctor.</p>	<p>EXTRA STRENGTH EXTRA FUERTE</p> <p>MuscleCare®</p> <p>PAIN RELIEVING GEL / GEL ALIVIANTE DEL DOLOR by / por el Dr. Chris Oswald</p>  <p>FOR MUSCLE & JOINT PAIN RELIEF PARA EL ALIVIO DEL DOLOR MUSCULAR Y ARTICULAR</p> <p>NET WT (Peso NETO) 3oz. (85g)</p>	<p>NDC# 24498-026-07</p> <p>Other Information: Store under normal storage conditions. Store away from children.</p> <p>Inactive Ingredients: Alcohol Denat., Acrylates Copolymer, Water, Eucalyptus Globulus Leaf Oil, Mentha Piperita (Peppermint) Oil, Peppermint Oil, Citronellol, Methyl Methacrylate, Benzyl Alcohol, Geranyl Ethyl Ether, Paraben (Ethyl Methylester) Extract, Glucosamine Sulfate, Chondroitin Sulfate, Magnesium Chloride, Tetrahydrocannabinol.</p> <p>Questions? 416-967-3746</p> <p>Distributed by MuscleCare Products 1 St. Clair Avenue East, Suite 1001, Toronto, ON M4T 2V7 Professional Therapy MuscleCare® is a registered trademark of Active & Innovative Inc.</p> <p>MADE IN USA</p> <p>Tiene alguna pregunta? Llame al 416-967-3746</p> <p>Distribuido por MuscleCare Products 1 St. Clair Avenue East, Suite 1001, Toronto, ON M4T 2V7 Professional Therapy MuscleCare® es una marca registrada de Active & Innovative Inc.</p> <p>HECHO EN LOS ESTADOS UNIDOS www.muscleandback.com</p>
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29215

3.25"

Real Feel Here



MuscleCare ROLL-ON USA

4.75"

<p>PROFESSIONAL THERAPY APLICADOR DE BOLA</p> <p>MuscleCare®</p> <p>ALIVIO EXTRA FUERTE DEL DOLOR por el Dr. Chris Oswald</p>	
<p>INFORMACIÓN FARMACOLÓGICA</p> <p>Principales Activos (% por peso)</p> <p>Alcator 4.0% Analgesico (alivio del dolor)</p> <p>Mentol 10.0% Analgesico (alivio del dolor)</p> <p>Usos: Para el alivio temporal de dolores musculares y articulares menores asociados con dolor de espalda simple, artritis, torceduras, hematomas y equimosis, etc.</p> <p>Advertencias:</p> <p>Únicamente para uso externo.</p> <ul style="list-style-type: none"> Precaución: Interrumpa el uso si desarrolla irritación excesiva de la piel. Evite el contacto con los ojos o las membranas mucosas. Si la condición empeora o si los síntomas persisten durante más de 7 días, o se curan y reaparecen al cabo de unos días, interrumpa el uso de este producto y consulte a un médico. No aplique el producto sobre heridas ni sobre la piel dañada. No utilice un vendaje ajustado. 	<p>Manténgase fuera del alcance de los niños.</p> <ul style="list-style-type: none"> Use únicamente según las indicaciones. No use el producto si está embarazada o en período de lactancia. En caso de ingestión, solicite asistencia médica o comuníquese con un Centro de Intoxicaciones de inmediato. <p>Indicaciones: Adultos y niños de 12 años o más: Usando el aplicador de bola, aplique una cantidad abundante del gel realizando masajes directos sobre la zona afectada no más de 3 a 4 veces por día. Los niños menores de 12 años no deben usar el producto; consulte a un médico.</p> <p>Otra Información: Guarde el producto en condiciones de almacenamiento normales, fuera del alcance de los niños.</p> <p>Ingredientes Inactivos: Denat. de alcohol, Acrylates Copolymer, el Agua, el Petróleo de Hoja de Eucalipto Globulus, Mentha Piperita (Mentol) el Petróleo, Geraniol de Propileno, la Glicerina, MCM (Methylmethacrylate), Extracto de Boswellia Seratta, la Extracta Paragonensis (Extracto de Compilgano de Yelita), Extracto, Sulfato de Glucosamina, Sulfato de Chondroitin, Cloruro de Magnesio, Tetrahydrocannabinol.</p>

3.25"

ARTWORK

MuscleCare Roll-on USA label Rev: 5
Date: 01-29-14

INSIDE LABEL

MUSCLECARE ROLL-ON LABEL USA

MuscleCare: Client
MuscleCare Roll-On BOX USA: Project
27001-3_usa_roll-onMC_label.pdf: File Name
01/29/14: Date
5: Version

Notes:
Chaged weight formats



Name/Date Approved by Regulatory Affairs

Name/Date Approved by Quality Assurance

Name/Date App'd. by Research and Dev.

STRENGTH

camphor, menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70039-283
Route of Administration	CUTANEOUS, TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	40 mg in 1 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	100 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ETHYL ACRYLATE/METHACRYLIC ACID/STEARETH-20 METHACRYLATE COPOLYMER (UNII: EPA1872R1N)	
WATER (UNII: 059QF0KO0R)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
CHONDROITIN SULFATE (CHICKEN) (UNII: 7VZ9466BAB)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
GLUCOSAMINE SULFATE (UNII: 1FW7WLR731)	
ALCOHOL (UNII: 3K9958V90M)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70039-283-07	1 g in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	06/01/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/01/2015	

Labeler - Active and Innovative Inc. (206978079)

Establishment

Name	Address	ID/FEI	Business Operations
PureTek Corp.		785961046	manufacture(70039-283)

Revised: 8/2016

Active and Innovative Inc.