# PROFESSIONAL THERAPY MUSCLECARE EXTRA STRENGTH- menthol, camphor 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

For Muscle and Joint Pain Relief

### **ACTIVE INGREDIENTS (% BY WEIGHT) PURPOSE**

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

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

### **USES:**

For the 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 onto 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:** Peppermint leaf oil (Mentha piperita), Eucalyptus globus leaf oil, Dimethyl sulfone (MSM), Boswellia Carterii Extract, Ilex Paraguariensis (Mate) leaf extract, Glucosamine sulfate, Chondroitin sulfte, Magnesium chloride, Tocopherol

(natural Vitamin E), Thymol crystals (5-methyl-2-(1-methylethyl)phenol), Water, Ethanol, Glycerin, UREA, Hydroxypropyl methylcellulose.

# Professional Therapy MuscleCare Extra Strength Pain Relieving Gel by Dr. Chris Oswald



Active Ingredients (% by weight) Purpose
Camphor 4.0%......Analgesic (pain relief)
Menthol 10.0%.....Analgesic (pain relief)

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

#### Warnings:

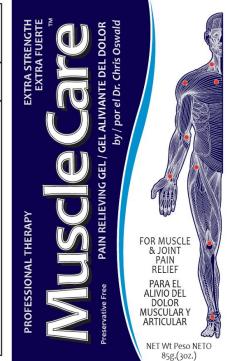
#### For external use only.

- 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 that 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: Peppermint leaf oil (Mentha piperita), Eucalyptus globulus leaf oil, Dimethyl sulfone (MSM), Boswellia Carterii Extract, liex Paraguariensis (Mate) leaf extract, Glucosamine sulfate, Chondroitin sulfate, Magnesium chloride, Tocopherol (natural Vitamin E), Thymol crystals (5-methyl-2-(1-methylethyl)phenol), Water, Ethanol, Glycerin, UREA, Hydroxypropyl methylcellulose.

# Questions? 416-967-3746 TOLL FREE: 1-844-784-7246

Distributed by: Muscle Care Products 1 St. Clair Avenue East., Suite 1001, Toronto, ON M4T 2V7 Professional Therapy Muscle Care™ is a registered trademark of Active & Innovative Inc.

MADE IN CANADA

Tiene alguna pregunta? Llame al 416-967-3746

Distribuido por. Muscle Care Products 1 St. Clair Avenue East., Suite 1001, Toronto, ON M4T 2V7 Professional Therapy Muscle Care™ es una marca registrada de Active & Innovative Inc.

FABRICADO EN LOS ESTADOS UNIDOS www.musclecare.net

4.72"



INFORMACIÓN FARMACOLÓGICA

 No aplique el producto sobre heridas ni sobre la piel dañada. No utilice un vendaie aiustado.

Mantenga fuera del alcance de los niños.

WEB DIRECTION

Principios Activos (% por peso) Proposito	Ш
Alcanfor 4.0%Analgésico (alivio del dolor)	Ш
Principius Activus (% por pesu) Propositu Acanfor 4.0%Analgésico (alivio del dolor) Mentol 10.0%Analgésico (alivio del dolor)	Ш
	-11

**Usos:** Para el alivio temporal de dolores musculares y articulares menores asociados con dolor de espalda simple, artritis, torceduras, hematomas y esquinces, etc.

#### Advertencias:

#### Únicamente para uso externo.

- Precaución: Interrumpa el uso si desarrolla irritación excesiva de la piel. Evite el contacto con los ojos o las membranas mucosas.
- Si la afección 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.

- Use unicamente segun 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.

Indicaciones: Adultos y niños de 12 años o más: Usando el aplicador de bola, aplíque una cantidad abundante del gel realizando masajes directamente 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.

Otra Información: Guarde el producto en condiciones de almacenamiento normales, fuera del alcance de los niños.

Ingredientes Inactivos: Copolímero de acrilatos, boswellia, sulfato de condroitina, alcohol desnaturalizado, cloruro del magnesio, aceite de eucalipto, sulfato de glucosamina, glicerina, ilex, metil sulfonil metano (MSM), aceite de menta peperina, propilenglicol, trietanolamina, agua.

# **INSIDE LABEL**

## PROFESSIONAL THERAPY MUSCLECARE EXTRA STRENGTH

menthol, camphor gel

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:70039-200

Route of Administration CUTANEOUS, TOPICAL

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

Inactive Ingredients	
Ingredient Name	Strength
EUCALYPTUS OIL (UNII: 2R040NI662)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
GLUCOSAMINE SULFATE (UNII: 1FW7WLR731)	
CHONDROITIN SULFATE (CHICKEN) (UNII: 7VZ 9466BAB)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
TOCOPHEROL (UNII: R0ZB2556P8)	
THYMOL (UNII: 3J50XA376E)	
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
GLYCERIN (UNII: PDC6A3C0OX)	
UREA (UNII: 8W8T17847W)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:70039- 200-02	85 g in 1 BOTTLE, WTH APPLICATOR; Type 0: Not a Combination Product	01/01/2017	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/01/2017	

# Labeler - Active and Innovative Inc. (206978079)

Establishment			
Name	Address	ID/FEI	Business Operations
Delta Pharma Inc.		200161730	manufacture(70039-200)

Establishment			
Name	Address	ID/FEI	Business Operations
PureTek Corporation		785961046	manufacture(70039-200)

Revised: 8/2021 Active and Innovative Inc.