# MUSCLECARE PAIN RELIEVING- camphor and menthol gel Active and Innovative

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.

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## **Drug Facts:**

## **Active Ingredients**

Camphor 4.0% Menthol 10.0%

#### **Purpose**

Analgesic (Pain Relief)

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 with in a few days, discontinue use of this products 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, message a liberal amount of gel directly on the affected area not more than 3 to 4 daily. Children under the age of 12: Do not use, consult a doctor.

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 (Methylsulfonymethane), Boswellia Serrata Extract, Glucosamine Sulfate, Chondroitin Sulfate, Magnesium Chloride, Triethanolamine

## BACK

# INFORMACIÓN FARMACOLÓGICA

# Principios Activos (% por peso) Propósito Alcanfor 4.0%.....Analgésico (alivio del dolor) Mentol 10.0%....Analgésico (alivio del dolor)

**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.
- No aplique el producto sobre heridas ni sobre la piel dañada.
   No utilice un vendaje ajustado.

#### Mantenga fuera del alcance de los niños.

- 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.

Indicaciones: Adultos y niños de 12 años o más: Usando el aplicador de bola, aplique 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: Denat. de alcohol, Acrylates Copolymer, el Agua, el Petróleo de Hoja de Eucalipto Globulus, Mentha Piperita (Menta) el Petróleo, Glicol de Propileno, la Glicerina, MSM (Methylsulfonylmethane), Extracto de Boswellia Serrata, la Encina Paraguariensis (Encina de Compañero de Yerba) Extracto. Sulfato de NDC# 24488-026-14

# **DRUG FACTS**

Active Ingredients (% by weight)		Purpose
Camphor 4.0%	Analgesic	(pain relief)
Menthol 10.0%		(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: Alcohol Denat., Acrylates
Copolymer, Water, Eucalyptus Globulus Leaf Oil, Mentha
Piperita (Peppermint) Oil, Propylene Glycol, Glycerin,
MSM (Methylsulfonylmethane), Boswellia Serrata Extract,
Ilex Paraguariensis (Yerba Mate Ilex) Extract,
Glucosamine Sulfate, Chondroitin Sulfate, Magnesium
Chloride, Triethanolamine

Questions? 416-967-3746
Distributed by: Muscle Care Products

Glucosamine, Sulfato de Chondróitin, Cloruro de Magnesio, Triethanolamine

Tiene alguna pregunta? Llame al 416-967-3746
Distribuito por: Muscle Care Products
1 St. Clair Avenue East., Suite 1001, Toronto, ON M4T 2V7
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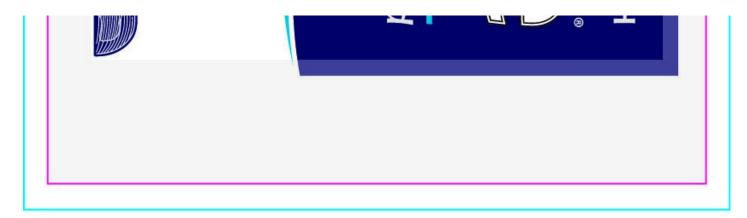
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Toronto, ON M4T 2V7
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Item# 27001-2ML





# **GEL FRONT**

## MUSCLECARE PAIN RELIEVING

camphor and menthol gel

Product I	nformation
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Product TypeHUMAN OTC DRUGItem Code (Source)NDC:24488-026

Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	.17 g in 1.7 g	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	.068 g in 1.7 g	

Inactive Ingredients		
Ingredient Name	Strength	
ALCOHOL (UNII: 3K9958V90M)		
POLYACRYLIC ACID (800000 MW) (UNII: D016NSZ87U)		
WATER (UNII: 059QF0KO0R)		
EUCALYPTUS OIL (UNII: 2R04ONI662)		
PEPPERMINT OIL (UNII: AV092KU4JH)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
GLYCERIN (UNII: PDC6A3C0OX)		
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)		
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)		
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)		
GLUCOSAMINE SULFATE (UNII: 1FW7WLR731)		
SULFATE ION (UNII: 7IS9N8KPMG)		
MAGNESIUM CHLO RIDE (UNII: 02F3473H9O)		
TROLAMINE (UNII: 9O3K93S3TK)		

# Item Code	Package Description	Marketing Start Dat	e Ma	rketing End Date
1 NDC:24488-026-14	1.7 g in 1 PACKET			
Marketing Info	rmation			
Marketing Info	rmation Application Number or Monogra	nph Citation Marketing	Start Date	Marketing End Date
Marketing Info		nph Citation Marketing 06/23/2011	Start Date	Marketing End Date

# **Labeler** - Active and Innovative (961956229)

# **Registrant -** Creations Garden Natural Products (961956229)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Creations Garden Natural Products		961956229	manufacture	

Revised: 6/2011 Active and Innovative