

**MUSCLE AND JOINT PAIN RELIEF GEL- menthol, eucalyptus globulus leaf oil gel**  
**Dimensional Merchandising 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.*

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**MUSCLE & JOINT PAIN RELIEF GEL**

***Drug Facts***

***Active Ingredients***

Menthol 5.0%

Eucalyptus Globulus Leaf Oil 3.25%

***Purpose***

Topical Analgesic

***Uses:***

Temporarily relieves the minor aches and pains of muscles and joints associated with: simple backache, arthritis, strains, bruises and sprains.

***Warnings:***

**For external use only.**

**Do Not Use:** On wounds or damaged skin, with a heating pad, or on a child under 12 years of age with arthritis-like conditions.

**Ask a Doctor Before Use If You Have:** Redness over the affected area.

**When Using This Product:** □Avoid contact with eyes or mucous membranes; do not bandage tightly.

**Stop Use and Ask Doctor If:** Condition worsens or symptoms persist for more than 7 days, if symptoms clear up and occur again within a few days, or if redness is present or excessive skin irritation develops.

**CAUTION:** Keep away from eyes. Wash hands and fingers thoroughly.

**Keep Out of Reach of Children:**

In case of accidental ingestion, seek professional assistance or contact a poison control center immediately.

***Directions:***

**Use only as directed.** □After use, wipe off applicator head and replace protective cap. Clean outside with damp cloth or paper towel. Do not rinse under or immerse in water.

**Adults and children 12 years of Age and older:** apply to affected area not more than 3 to 4 times daily.

**Children Under 12 years of Age:** □consult a doctor.

**Other Information:** ☐Store between 20 and 25 °C (68 and 77 °F)

**Other Ingredients:**

Water, Alcohol Denatured, Glycerin, Piper Methysticum Leaf/Root/Stem Extract, Calendula Officinalis Flower Extract, Arnica Montana Flower Extract, Carbomer, Butylene Glycol, Propylene Glycol, Polysorbate 20, Chlorphenesin, Sodium Hydroxide, Sodium Benzoate, Potassium Sorbate.

**NatureWell™ CLINICAL**

**WITH KAVA EXTRACT**

**MUSCLE STRAINS**

**JOINT PAIN**

**STRAINS AND CRAMPS**

**☐TEMPORARY PAIN RELIEF • SOOTHES ACHES & PAINS • QUICK VANISHING ODOR**

**FAST-ACTING • NON-GREASY • QUICK-DRY FORMULA**

**HANDS FREE ROLLER BALL APPLICATION**

**MESS-FREE MASSAGING APPLICATOR**

**No Parabens • Dye-Free**

**Not Tested on Animals**

**Formula Made in the USA**

☐Soothe aching muscles and joints with NatureWell™ Clinical

In an easy to use roll-on applicator, this product glides on for targeted, cooling relief. Formulated with 5% Menthol and 3.25% Eucalyptus Oil to reduce aches and pain. This no-mess, fast acting gel temporarily alleviates any aches or pains. Great for muscle strains, sprains and cramps.

**☐BENEFITS**

- FAST RELIEF
- SOOTHES ACHES AND PAINS
- QUICK VANISHING ODOR
- NO MESS APPLICATOR

**☐KEY INGREDIENTS**

- **5% Menthol** - ☐Helps relieve joint and muscle pain
- **☐3.25% Eucalyptus Oil** ☐- Helps relieve sore, stiff muscles
- **☐Kava Extract** ☐- Helps provide additional cooling benefits
- **☐Arnica & Calendula Extracts** ☐- Helps calm and comfort

**☐DISTRIBUTED BY:**

**NATUREWELL™**

**PHOENIX, AZ 85016**

**Packaging**

**TUBE LABEL**

**Drug Facts**

<b>Active Ingredients</b>	<b>Purpose</b>
Menthol 5.0% Eucalyptus Globulus Leaf Oil 3.25%	Topical Analgesic Topical Analgesic

**Uses:** Temporarily relieves the minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, tension and sprains.

**Warnings:**  
For external use only.

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**CAUTION:** Keep away from eyes. Wash hands and fingers thoroughly.

**Directions:**  
Use only as directed. After use, wipe off applicator head and replace protective cap. Clean outside with damp cloth or paper towel. Do not rise under or immerse in water.  
Adults and children 12 Years of Age and older, apply to affected area not more than 3 to 4 times daily.  
Children Under 12 Years of Age: contact a doctor.

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**Other Ingredients:** Water, Alcohol Denatured, Glycerin, Piper Methystronium Lauryl Sulfate/Stearyl Alcohol, Calendula Officinalis Flower Extract, Arnica Montana Flower Extract, Camphor, Butylene Glycol, Propylene Glycol, Polypropylene Glycol, Chlorphenesin, Sodium Hydroxide, Sodium Benzoate, Potassium Sorbate.

DISTRIBUTED BY:  
NATUREWELL™  
PHOENIX, AZ 85016  
FORMULA MADE IN THE USA

**OUTER LABEL**

**WITH KAVA EXTRACT**

**NatureWell™ CLINICAL**

**MUSCLE & JOINT PAIN RELIEF GEL**

MUSCLE STRAINS  
JOINT PAIN  
SPRAINS AND CRAMPS

MESS-FREE MASSAGING APPLICATOR

TEMPORARY PAIN RELIEF • SOOTHES ACHES & PAINS • QUICK VANISHING ODOR

FAST-ACTING • NON-GREASY • QUICK-DRY FORMULA  
HANDS FREE ROLLER BALL APPLICATION

NET WT. 3.4 OZ / 96 G EACH

**WITH KAVA EXTRACT**

**NatureWell™ CLINICAL**

**MUSCLE & JOINT PAIN RELIEF GEL**

Soothe aching muscles and joints with NatureWell™ Clinical Muscle & Joint Pain Relief Gel.

In an easy to use roll-on applicator, this product glides on for targeted, cooling relief. Formulated with 5% Menthol and 3.25% Eucalyptus Oil to reduce aches and pain. This no-mess, fast acting gel temporarily alleviates any aches or pains. Great for muscle strains, sprains and cramps.

**BENEFITS**

- FAST RELIEF
- SOOTHES ACHES AND PAINS
- QUICK VANISHING ODOR
- NO MESS APPLICATOR

**KEY INGREDIENTS**

- 5% Menthol - Helps relieve joint and muscle pain
- 3.25% Eucalyptus Oil - Helps relieve sore, stiff muscles
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- Arnica & Calendula Extracts - Helps calm and comfort

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No Parabens • Dye-Free  
Not Tested on Animals  
Formula Made in the USA

TEMPORARY PAIN RELIEF • SOOTHES ACHES & PAINS • QUICK VANISHING ODOR

DISTRIBUTED BY:  
NATUREWELL™  
PHOENIX, AZ 85016  
FORMULA MADE IN THE USA

**MUSCLE AND JOINT PAIN RELIEF GEL**

menthol, eucalyptus globulus leaf gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61383-701
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL -	MENTHOL, UNSPECIFIED	5 g in 100 g

UNII:L7T10EIP3A)	FORM	3.25 g in 100 g
<b>EUCALYPTUS OIL</b> (UNII: 2R04ONI662) (EUCALYPTUS OIL - UNII:2R04ONI662)	EUCALYPTUS OIL	3.25 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PIPER METHYSTICUM ROOT</b> (UNII: BOW48C81XP)	
<b>CALENDULA OFFICINALIS FLOWER</b> (UNII: P0M7O4Y7YD)	
<b>ARNICA MONTANA FLOWER</b> (UNII: OZ0E5Y15PZ)	
<b>CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: 4Q93RCW27E)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61383-701-01	2 in 1 BLISTER PACK	11/16/2016	
1	NDC:61383-701-96	96 g in 1 TUBE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	11/16/2016	

**Labeler** - Dimensional Merchandising Inc. (076693183)

### Establishment

Name	Address	ID/FEI	Business Operations
Dimensional Merchandising Inc.		076693183	manufacture(61383-701)

Revised: 11/2016

Dimensional Merchandising Inc.