

CBDMEDIC MASSAGE THERAPY- camphor and menthol. oil
AIDANCE SKINCARE & TOPICAL SOLUTIONS, LLC

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.

CBDMEDIC Massage Therapy Oil

Active Ingredients and Purpose

Camphor 3%, Menthol 4% (External Analgesics)

Uses

Temporarily relieves 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. When using this product: • avoid contact with eyes or mucous membranes • do not bandage tightly or use with a heating pad. **Stop use and ask a doctor if:** • condition worsens, or symptoms persist for more than 7 days • symptoms clear up and occur again within a few days • excessive skin irritation develops.

Keep out of reach of children

If swallowed, get medical help or contact a poison control center immediately.

Directions

Adults and children 12 years of age and older: massage oil into affected area not more than 3 to 4 times daily. Children under 12 years of age: ask a doctor.

Inactive ingredients

Argan oil, Coconut Oil (MCT oil), Cotton seed Oil, Frankincense Oil, Hemp extract*, Honeysuckle Oil, Jojoba seed oil, Myrrh Oil. *(THC-free hemp extract)

PRINCIPAL DISPLAY PANEL

<p>DRUG FACTS</p> <p>Active Ingredients: Camphor 3% and Menthol 4% (External Analgesic) Uses: Temporarily relieves minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises and sprains.</p> <p>Warnings: For external use only. Do not use on wounds or damaged skin. When using this product:</p> <ul style="list-style-type: none"> • avoid contact with eyes or mucous membranes • do not bandage tightly or use with a heating pad <p>Stop use and ask a doctor if: • condition worsens, or symptoms persist for more than 7 days</p> <ul style="list-style-type: none"> • symptoms clear up and occur again within a few days • excessive skin irritation develops <p>Keep out of reach of children. If swallowed, get medical help or contact a poison control center immediately.</p> <p>Directions: Adults and children 12 years of age and older: massage oil into affected area not more than 3 to 4 times daily. Children under 12 years of age: ask a doctor.</p> <p>Inactive Ingredients: Argan oil, coconut oil (MCT oil), cotton seed oil, frankincense oil, hemp extract*, honeysuckle oil, jojoba seed oil, myrrh oil. *(THC-free hemp extract)</p>		  <p>CBDMEDIC™ Revolutionary. SAFE.™</p>	<p>THE PAIN RELIEF REVOLUTION</p> <p>CBDMEDIC™ Massage Therapy Oil was developed after years of research with a mission to provide faster, stronger and longer-lasting relief from muscle and joint pain. This powerful analgesic massage oil will keep you moving. We use only naturally-derived analgesic ingredients. Our natural emollients and essential oils help enhance absorption*. This product is infused with THC-free hemp extract.</p> <p><small>* published studies available on request</small></p> <p>Only the Highest Quality</p> <p>CBDMEDIC™ products are produced in conformance with the FDA requirements for topical analgesics and are made in an FDA-audited manufacturing facility. This helps ensure the highest quality controls in raw ingredients, manufacturing and packaging.</p>
<p>Our Mission: FASTER, STRONGER, LONGER-LASTING, PAIN RELIEF</p>		<p>MASSAGE THERAPY OIL</p>	
 <p>CONTACT US (401) 216-8080 www.cbd-medic.com</p> <p><small>© Copyright 2018. All rights reserved. CBDMEDIC™, the leaf logo™, Revolutionary, SAFE.™ and Experience the Pain Relief Revolution™ are trademarks of Abacus Health Products, Inc. Patents Pending. Manufactured in the USA. Distributed by Abacus Health Products, Inc., Woonsocket, RI, 02895.</small></p>		<p>EXPERIENCE The Pain Relief REVOLUTION™</p> <p>Camphor 3% Menthol 4%</p> <p>With Natural Ingredients</p> <p>Net WT 4 OZ</p>	

CBDMEDIC MASSAGE THERAPY

camphor and menthol. oil

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:249 09-727
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	30 g in 1 mL
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	40 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ARGAN OIL (UNII: 4V59G5UW9X)	
COCONUT OIL (UNII: Q9L0O73W7L)	
COTTONSEED OIL (UNII: H3E878020N)	
FRANKINCENSE OIL (UNII: 67ZYA5T02K)	
HEMP (UNII: TD1MUT01Q7)	
LONICERA CONFUSA WHOLE (UNII: 22L2C7GWOA)	

JOJOBA OIL (UNII: 724GKU717M)

MYRRH OIL (UNII: H74221J5J4)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24909-727-04	1 in 1 CARTON	10/01/2018	
1		118 mL in 1 BOTTLE; 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	10/01/2018	

Labeler - AIDANCE SKINCARE & TOPICAL SOLUTIONS, LLC (018950611)

Establishment

Name	Address	ID/FEI	Business Operations
Aidance Skincare & Topical Solutions, LLC		018950611	manufacture(24909-727) , label(24909-727)

Revised: 11/2018

AIDANCE SKINCARE & TOPICAL SOLUTIONS, LLC