

PAIN RELEASE- menthol oil
Natures Formulae Health Products Ltd.

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.

Pain Release Topical Analgesic Massage Oil

DRUG FACTS

Active ingredient

Menthol 1.37%

Purpose Topical Analgesic

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

Warnings

For external use only.

Flammable. Keep away from fire or flame

Do not use

- on wounds or damaged skin
- if epileptic
- with high blood pressure

When using this product

- avoid contact with the eyes.
- do not bandage tightly

Stop use and ask a doctor if

condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days.

If pregnant or breast-feeding,

do not use this product.

Keep out of reach of children.

If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

- 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.

Inactive ingredients

Anthemis nobilis flower oil, eucalyptus oil, lavender oil, melaleuca leucadendron cajaput oil, origanum majorana leaf oil, peppermint oil, prunus armeniaca (apricot) kernel oil, rosmarinus officinalis (rosemary) leaf oil, tocopherol, and vitis vinifera (grape) seed oil.

Questions?

1-877-275-7253

☐ Distributed by: **SAJE NATURAL WELLNESS** 500-88 E. Pender St. Vancouver, BC Canada V6A 3X3 | saje.com | **1-877-275-7253** | Made by our friends in Canada

DO NOT USE IF SECURITY SEAL AROUND BOTTLE IS BROKEN OR MISSING.

SKU 415401

We support recycling. Please recycle where possible.

Pain Release Topical Analgesic Massage Oil

Saje® Natural Wellness

Pain Release

Topical Analgesic Massage Oil

6.8 fl. oz. | 200 ml and 1.4 fl.oz | 40ml

SEE OUTER LABEL FOR FULL LABELING.
DIRECTIONS: ADULTS AND CHILDREN 12 YEARS & OLDER: APPLY TO AFFECTED AREA NOT MORE THAN 3 TO 4 TIMES DAILY. **CHILDREN UNDER 12 YEARS:** CONSULT A DOCTOR.

ACTIVE INGREDIENT: MENTHOL 1.37% (FROM PEPPERMINT OIL).

WARNINGS: FOR EXTERNAL USE ONLY. FLAMMABLE: KEEP AWAY FROM FIRE/FLAME. **DO NOT USE** • ON WOUNDS/DAMAGED SKIN • IF EPILEPTIC • WITH HIGH BLOOD PRESSURE. **DURING USE** • AVOID CONTACT WITH EYES • DO NOT BANDAGE TIGHTLY. **STOP USE & ASK A DOCTOR IF** • CONDITION WORSENS • SYMPTOMS PERSIST FOR MORE THAN 7 DAYS. **IF PREGNANT/BREAST-FEEDING,** DO NOT USE THIS PRODUCT. **KEEP OUT OF REACH OF CHILDREN.** IF PRODUCT IS SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY. **DO NOT USE IF SECURITY SEAL AROUND BOTTLE IS BROKEN OR MISSING.**

Distributed by: SAJE NATURAL WELLNESS
500 - 88 EAST PENDER ST. VANCOUVER, BC CANADA V6A 3X3
SAJE.COM | 1-877-275-7253 | MADE BY OUR FRIENDS IN CANADA

Saje®

NATURAL WELLNESS



pain release
topical analgesic
massage oil

SKU 414701

WE SUPPORT RECYCLING.
PLEASE RECYCLE WHERE POSSIBLE.

14 fl.oz. | 40 ml



IMPORTANT: READ ALL PRODUCT INFORMATION BEFORE USING. KEEP THIS PACKAGE FOR FULL INFORMATION.

Drug Facts

Active ingredient	Purpose
Menthol 1.37%	Topical Analgesic

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

Warnings
 For external use only.
 Flammable. Keep away from fire or flame.
 Do not use
 • on wounds or damaged skin
 • if epileptic
 • with high blood pressure

When using this product
 • avoid contact with the eyes
 • do not bandage tightly

Stop use and ask a doctor if condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days.

If pregnant or breast-feeding, do not use this product.

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions
 • 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.

Inactive ingredients Anthemis nobilis flower oil, eucalyptus oil, lavender oil, melaleuca leucadendron cajaput oil, origanum majorana leaf oil, peppermint oil, prunus armeniaca (apricot) kernel oil, rosmarinus officinalis (rosemary) leaf oil, tocopherol, and vitis vinifera (grape) seed oil.

Questions? 1-877-275-7253

Distributed by: SAJE NATURAL WELLNESS
 500-88 E. PENDER ST. VANCOUVER, BC CANADA V6A 3X3
 SAJE.COM | 1-877-275-7253 | MADE BY OUR FRIENDS IN CANADA
 DO NOT USE IF SECURITY SEAL AROUND BOTTLE IS BROKEN OR MISSING.

SKU 415401

WE SUPPORT RECYCLING.
 PLEASE RECYCLE WHERE POSSIBLE.



Saje[®]
 NATURAL WELLNESS



pain release
 topical analgesic
 massage oil

6.8 fl.oz. | 200ml

PAIN RELEASE

menthol oil

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69204-008
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	12.18 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CHAMAEMELUM NOBILE FLOWER OIL (UNII: UB27587839)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
CAJUPUT OIL (UNII: J3TO6BUQ37)	
SWEET MARJORAM OIL (UNII: ICH7BE016E)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
APRICOT KERNEL OIL (UNII: 54JB35T06A)	
ROSEMARY OIL (UNII: 8LGU7VM393)	
TOCOPHEROL (UNII: R0ZB2556P8)	
GRAPE SEED OIL (UNII: 930MLC8XGG)	

Product Characteristics

Color	white (clear)	Score	
Shape	FREEFORM (oil)	Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69204-008-10	1 in 1 BOX	10/16/2016	
1		200 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
2	NDC:69204-008-11	40 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/16/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/16/2016	

Labeler - Natures Formulae Health Products Ltd. (241385587)**Establishment**

Name	Address	ID/FEI	Business Operations
------	---------	--------	---------------------

Revised: 10/2016

Natures Formulae Health Products Ltd.