

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 Oil Blend (30 ml, 10 ml, 6 ml)

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

DRUG FACTS

Active ingredient

Menthol 1.98%

Purpose 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.

- Not recommended for children under 12 years of age.

Inactive ingredients

Anthemis nobilis flower oil, eucalyptus oil, lavender oil, melaleuca leucadendron cajaput oil, origanum majorana leaf oil, peppermint oil, rosmarinus officinalis (rosemary) leaf oil, 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 in Canada

Pain Release 30 ml

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

SKU 10301

Pain Release 10 ml

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

SKU 431201

Pain Release 6 ml

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

SKU 442501

Pain Release Topical Analgesic Oil Blend 30 ml

Saje® Natural Wellness

Pain Release

Topical Analgesic Oil Blend

1 fl. oz. | 30 ml



Pain Release Topical Analgesic Oil Blend 10 ml

Saje® Natural Wellness

Pain Release

Topical Analgesic Oil Blend

0.34 fl. oz. | 10 ml

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

SKU 431201

pain release

Saje®
NATURAL WELLNESS



pain release
topical analgesic
oil blend

0.34 fl.oz. | 10 ml

Pain Release Topical Analgesic Oil Blend 6 ml

Saje® Natural Wellness

Pain Release

Topical Analgesic Oil Blend

0.2 fl. oz. | 6 ml

pain release

pain release

Saje[®]
NATURAL WELLNESS

pain release
topical analgesic
oil blend

0.2 fl.oz. | 6 ml

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Drug Facts (continued)

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PAIN RELEASE

menthol oil

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69204-007
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	17.62 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)	
ROSEMARY OIL (UNII: 8LGU7VM393)	
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:69204-007-03	1 in 1 BOX	10/16/2016	
1		30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
2	NDC:69204-007-04	1 in 1 BOX	10/16/2016	
2		10 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
3	NDC:69204-007-05	1 in 1 BOX	10/16/2016	
3		6 mL in 1 BOTTLE, DROPPER; 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	10/16/2016	

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

Name	Address	ID/FEI	Business Operations
Natures Formulae Health Products Ltd.		241385587	manufacture(69204-007)

Revised: 10/2018

Natures Formulae Health Products Ltd.