# ROAD TO WELLNESS- menthol Saje Natural Business 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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### Road to Wellness Cooling Relief Convenience Kit (13.5 g, 2 x 6 ml)

Kit Contains 3 SAJE FAVORITES:

TRAUMA LESS Itopical analgesic ointment

PAIN RELEASE topical analgesic oil blend

peppermint halo COOLING & SOOTHING OIL BLEND FOR THE HEAD

IMPORTANT: FOR EACH PRODUCT, READ ALL PRODUCT INFORMATION ON OUTER AND INNER BOX FLAP BEFORE USING. KEEP THIS PACKAGE FOR FULL INFORMATION.

DO NOT USE IF THE FOLLOWING SECURITY FEATURES ARE BROKEN OR MISSING:

SEAL AROUND TIN (OINTMENT) | SEAL AROUND BOTTLE (OIL BLENDS)

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

We support recycling. Please recycle where possible

SKU 22280201

LIFT HERE TO CONTINUE TO READ IMPORTANT PRODUCT INFORMATION ON ALL PRODUCTS.

GET READY FOR WELLNESS

#### **Drug Facts**

#### Active ingredient

Menthol 1.27%

**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.** IKeep away from fire or flame.

#### Do not use

- Ion wounds or damaged skin
- if allergic to plants of the asteraceae/compositae/daisy family.

#### 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,

ask a doctor before use.

#### 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 times daily.
- Not recommended for children under 12 years of age.

#### **Inactive ingredients**

Arnica montana flower extract, beeswax (yellow), olive oil, and peppermint oil.

### PAIN RELEASE - topical analgesic oil blend

#### **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.

#### Pain Release - topical analgesic oil blend

### Apply to muscles & joints experiencing minor aches & pains, as directed:

- A Shoulders
- B Neck
- C Back (upper/middle/lower)
- D Elbows
- E Hands
- F Soles of Feet
- G Hips
- H Thighs
- I Knees
- J Calves

#### SOOTHING OIL BLEND

## peppermint halo COOLING & SOOTHING OIL BLEND FOR THE HEAD

### Apply to the following areas:

- A Along hairline
- B Neck

#### C - Shoulders

**Directions for use:** Apply as desired to entire hairline, creating a halo effect. Apply to neck and shoulders for extra cooling and relaxation. Avoid eyes and mucous membranes. For prolonged use, consult a doctor.

**Ingredients:** Mentha piperita (peppermint) oil, eucalyptus globulus leaf oil, melaleuca leucadendron cajaput oil, rosmarinus officinalis (rosemary) leaf oil, lavandula angustifolia (lavender) oil, and vetiveria zizanoides root oil.

#### Warnings:

- Keep out of reach of children.
- For external use only. if swallowed, seek urgent care/call poison control.
- If skin sensitization occurs, rinse with vegetable oil.
- Avoid eyes & mucous membranes; if contact occurs, rinse with vegetable oil.
- Do not use if pregnant/breastfeeding, with high/low blood pressure, or if epileptic.
- If allergic reaction occurs, stop use & consult a doctor.

Saje is committed to providing 100% natural products containing pure essential oils and ingredients derived from mineral and botanical sources. Saje products are not tested on animals and do not contain any artificial or synthetic chemicals, preservatives, fragrances or colors.

#### ROAD TO WELLNESS

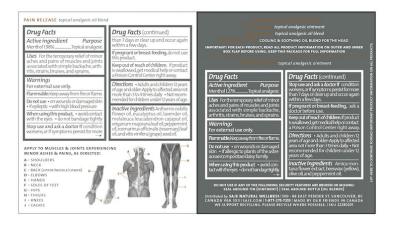
cooling relief convenience kit

1 TOPICAL ANALGESIC OINTMENT 0.47 OZ. | 13.5 g

1 TOPICAL ANALGESIC OIL BLEND 0.2 FL.OZ. | 6 mL

1 OIL BLEND 0.2 FL.OZ. | 6 mL







#### **ROAD TO WELLNESS**

menthol kit

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70983-017

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NE	OC:70983-017-19	1 in 1 KIT	10/16/2016	

Quan	Quantity of Parts			
Part #	Package Quantity	Total Product Quantity		
Part 1	1 CANISTER	13.5 g		
Part 2	1 BOTTLE, DROPPER	6 mL		
Part 3	1 BOTTLE, DROPPER	6 mL		

## Part 1 of 3

## TRAUMA LESS

menthol ointment

### **Product Information**

Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MENTHOL (UNII: L7T10 EIP3A) (MENTHOL - UNII:L7T10 EIP3A)	MENTHOL	12.7 mg in 1 g	

Inactive Ingredients		
Ingredient Name	Strength	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)		
YELLOW WAX (UNII: 2ZA36H0S2V)		
OLIVE OIL (UNII: 6 UYK2W1W1E)		
PEPPERMINT O IL (UNII: AV092KU4JH)		

Product Characteristics			
Color	yello w	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

l	Packaging			
l	# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
l	1	13.5 g in 1 CANISTER; Type 1: Convenience Kit of Co-Package		

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

## Part 2 of 3

### **PAIN RELEASE**

menthol oil

### **Product Information**

Route of Administration TOPICAL

## Active Ingredient/Active Moiety

- 1	J J		
	Ingredient Name	Basis of Strength	Strength
	MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHO L	17.62 mg in 1 mL

Inactive Ingredients		
Ingredient Name	Strength	
CHAMAEMELUM NOBILE FLOWER OIL (UNII: UB27587839)		
EUCALYPTUS OIL (UNII: 2R04ONI662)		
LAVENDER O IL (UNII: ZBP1YXW0H8)		
CAJUPUT OIL (UNII: J3TO6BUQ37)		
SWEET MARJORAM OIL (UNII: ICH7BE016E)		
PEPPERMINT OIL (UNII: AV092KU4JH)		
ROSEMARY OIL (UNII: 8LGU7VM393)		
GRAPE SEED OIL (UNII: 930 MLC8 XGG)		

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

Pa	ckaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		6 mL in 1 BOTTLE, DROPPER; Type 1: Convenience Kit of Co-Package		

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

## Part 3 of 3

### PEPPERMINT HALO

other skin care preparations

## **Product Information**

Other Ingredients			
Ingredient Kind	Ingredient Name	Quantity	
INGR	PEPPERMINT OIL (UNII: AV092KU4JH)		
INGR	EUCALYPTUS OIL (UNII: 2R040NI662)		
INGR	CAJUPUT OIL (UNII: J3TO6BUQ37)		
INGR	ROSEMARY OIL (UNII: 8LGU7VM393)		
INGR	LAVENDER OIL (UNII: ZBP1YXW0H8)		
INGR	VETIVER OIL (UNII: 9 M9 P32 M0 1L)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		6 mL in 1 BOTTLE, DROPPER; Type 1: Convenience Kit of Co-Package		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic			

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

# Labeler - Saje Natural Business Inc. (203413380)

Establishment				
Name	Address	ID/FEI	Business Operations	
Natures Formulae Health Products Ltd.		241385587	manufacture(70983-017)	

Revised: 10/2016 Saje Natural Business Inc.