

**PAIN RELEASE- menthol granule**  
**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.*

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**Pain Release Bath Salt Soak (620 g, 120 g)**

***DRUG FACTS***

***Active ingredient***

Menthol 0.16%

***Purpose*** External Analgesic

***Uses*** For the temporary relief of pain and itching associated with scrapes, insect bites, and minor skin irritations.

***Warnings***

**For external use only.**

**Do not use**

- if epileptic
- with high blood pressure

**When using this product,**

avoid contact with the eyes.

**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 by dissolving 2 teaspoons of salt soak in warm water and soaking area  
  
not more than 3 to 4 times daily.
- Children under 12 years of age: consult a doctor.

## Inactive ingredients

Anthemis nobilis flower oil, cinnamomum camphora (camphor) bark oil, corn starch, epsom salt, eucalyptus oil, lavender oil, organum majorana leaf oil, peppermint oil, rosmarinus officinalis (rosemary) leaf oil, sea salt, and sodium bicarbonate.

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 620 g

**DO NOT USE IF SAJE SEAL ON BOTTLE'S OPENING IS BROKEN OR MISSING.**

SKU 427901

## Pain Release 120 g

**DO NOT USE IF TEAR NOTCH SECURITY SEAL ON ZIPPERED BAG INSIDE IS DAMAGED OR MISSING**

SKU 423501

## Pain Release Bath Salt Soak 620 g

Saje® Natural Wellness

## Pain Release

## Pain Relieving Bath Salt Soak

net wt. 21.9 oz. | 620 g



## Pain Release Bath Salt Soak 120 g

Saje® Natural Wellness

## Pain Release

## Pain Relieving Bath Salt Soak

net wt. 4.2 oz. | 120 g



## PAIN RELEASE

menthol granule

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69204-005
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1.6 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
CHAMAEMELUM NOBILE FLOWER OIL (UNII: UB27587839)	
CAMPHOR OIL (UNII: 75IZZ8Y727)	
STARCH, CORN (UNII: O8232NY3SJ)	
MAGNESIUM SULFATE HEPTAHYDRATE (UNII: SK47B8698T)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	

SWEET MARJORAM OIL (UNII: ICH7BE016E)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
ROSEMARY OIL (UNII: 8LGU7VM393)	
SEA SALT (UNII: 87GE52P74G)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	

### Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69204-005-06	620 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/16/2016	
2	NDC:69204-005-07	1 in 1 PACKET	10/16/2016	
2		120 g in 1 POUCH; 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(69204-005)