

PAIN RELEASE- menthol granule
Saje Natural Business Inc.

Pain Release Bath Salt Soak

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, origanum 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 120 g

Saje Natural Wellness

Pain Release

Pain Relieving Bath Salt Soak

net wt. 4.2 oz. | 120 g



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 Pain Relieving Bath Salt Soak net wt. 10.6 oz. | 300 g

Saje Natural Wellness

Pain Release

Pain Relieving Bath Salt Soak

net wt. 10.6 oz. | 300 g

 Pain Release <hr/> pain relieving bath salt soak <hr/> <i>net wt</i> 10.6 oz 300 g	<p>Drug Facts</p> <table border="1"> <tr> <td>Active ingredient</td> <td>Purpose</td> </tr> <tr> <td>Menthol 0.16%</td> <td>External Analgesic</td> </tr> </table> <p>Uses For the temporary relief of pain and itching associated with scrapes, insect bites and minor skin irritations.</p> <p>Warnings For external use only.</p> <p>Do not use • if epileptic • with high blood pressure</p> <p>When using this product, avoid contact with the eyes.</p> <p>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.</p> <p>If pregnant or breast-feeding, do not use this product.</p>	Active ingredient	Purpose	Menthol 0.16%	External Analgesic	<p>Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.</p> <p>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.</p> <p>Inactive ingredients Anthemis nobilis flower oil, cinnamomum camphora (camphor) bark oil, corn starch, epsom salt, eucalyptus oil, lavender oil, origanum majorana leaf oil, peppermint oil, rosmarinus officinalis (rosemary) leaf oil, sea salt, sodium bicarbonate.</p> <p><small>DO NOT USE IF SECURITY SEAL IS BROKEN OR MISSING.</small></p> <p><small>Distributed by: SAJE NATURAL WELLNESS 22 EAST 5TH AVE VANCOUVER, BC CANADA V5T 1G8 SAJE.COM #SARNWELLNESS MADE IN CANADA QUESTIONS? CALL 1-877-275-7253 SKU 705607 please recycle where possible</small></p>
Active ingredient	Purpose					
Menthol 0.16%	External Analgesic					

PAIN RELEASE

menthol granule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70983-004
Route of Administration	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:70983-004-06	620 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/16/2016	
2	NDC:70983-004-07	1 in 1 PACKET	10/16/2016	
2		120 g in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:70983-004-05	300 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/29/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	10/16/2016	

Labeler - Saje Natural Business Inc. (080465432)

Establishment

Name	Address	ID/FEI	Business Operations
Natures Formulae Health Products Ltd.		241385587	manufacture(70983-004)