

EXTRA STRENGTH- menthol and methyl salicylate 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.

Extra Strength

Menthol 10.5%, Methyl Salicylate 13.4%

External analgesic (Counterirritant)

For the temporary relief of minor aches and pains of muscles and joints associated with:

• simple back ache • arthritis • strains • bruise • sprains

For external use only

Flammable

Keep away from fire and flame

Do not use on wounds or damaged skin

Do not bandage tightly

Do not use if you are allergic to plants of the asteraceae/compositae/daisy family

Avoid contact with eyes and mucous membranes; if this happens, rinse with vegetable oil

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 breastfeeding, ask a health professional before use.

Keep out of reach of children. If product swallowed, get medical help or contact a Poison Control Centre right way.

Adults: apply to affected area no more than 3 to 4 times daily.

Store at room temperature.

Anthemis nobilis flower oil, elettaria cardamomum seed oil, kunzea ambigua branch/leaf/twig oil, lavender oil, origanum majorana leaf oil, rosmarinus officinalis (rosemary) leaf oil, syzygium aromaticum bud oil, vitis vinifera (grape) seed oil

Important: Read all product information before using. Keep this package for full information.

Do not use if security seal around bottle is broken or missing.

Questions? Call 1-877-275-7253

distributed by: saje natural wellness 22 east 5th ave vancouver, bc canada v5t 1g8
saje.com 1-877-ask-saje @sajewellness

Extra Strength

Pain Relieving Oil Blend
1.5 fl oz (45 ml)

Extra Strength USA Artwork_Box

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

Drug Facts

Active ingredients	Purpose
Menthol 10.5% }	External analgesic
Methyl salicylate 13.4% }	(Counterirritant)

Uses For the temporary relief of minor aches and pains of muscles and joints associated with: • simple back ache • arthritis • strains • bruise • sprains

Warnings

For external use only.

Flammable. Keep away from fire or flame.

Do not • use on wounds or damaged skin • bandage tightly • if allergic to plants of the asteraceae/compositae/daisy family

When using this product, avoid contact with the eyes and mucous membranes; if this happens, rinse with vegetable oil.

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 health professional 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: Apply to affected area no more than 3 to 4 times daily.

Other Information Store at room temperature.

Inactive ingredients Anthemis nobilis flower oil, elettaria cardamomum seed oil, eugenia caryophyllus (clove) bud oil, kunzea ambigua branch/leaf/twig oil, lavender oil, organum majorana leaf oil, rosmarinus officinalis (rosemary) leaf oil, vitis vinifera (grape) seed oil.



Extra Strength
pain relieving oil blend



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

Distributed by:

SAJE NATURAL WELLNESS 22 EAST 5TH AVE VANCOUVER, BC CANADA
V5T 1G8 | SAJE.COM | @SAJEWELLNESS | MADE BY OUR FRIENDS IN CANADA
QUESTIONS? CALL 1-877-275-7253 | I'M MADE FROM RECYCLED PAPER.

SKU 701083 please recycle where possible

LOT NUMBER
PLACEMENT

1.5 fl oz

45 ml

EXTRA STRENGTH

menthol and methyl salicylate oil

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:69204-027

Route of Administration	TOPICAL
--------------------------------	---------

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	94.41 mg in 1 mL
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	123.74 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CHAMAEMELUM NOBILE (UNII: 7NF3GE7IWR)	
KUNZEA AMBIGUA WHOLE (UNII: R09L2486DI)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
ORIGANUM MAJORANA (UNII: R40XM3HU5X)	
ROSEMARY OIL (UNII: 8LGU7VM393)	
TRIFOLIUM PRATENSE FLOWER (UNII: 4JS0838828)	
GRAPE SEED OIL (UNII: 930MLC8XGG)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
BETULA LENTA BARK (UNII: J689T0DVJQ)	
ELETTARIA CARDAMOMUM WHOLE (UNII: KH2S76267N)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69204-027-01	1 in 1 BOX	05/13/2019	
1		45 mL in 1 BOTTLE, WITH APPLICATOR; 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	05/13/2019	

Labeler - NATURES FORMULAE HEALTH PRODUCTS LTD. (241385587)

Establishment

Name	Address	ID/FEI	Business Operations
Natures Formulae Health Products Ltd.		241385587	manufacture(69204-027)