

COMFORT AND EASE- menthol
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.

Comfort and Ease Oil Blend Convenience Kit (3 x 6 ml)

GET READY FOR WELLNESS

Reach for this convenient trio of oil blends to support your wellness, naturally.

Kit Contains 3 popular saje oil blends:

FORTIFY antitussive (cough suppressant) oil blend rub

SWEET COMFORT antitussive (cough suppressant) oil blend rub

inhale SOOTHING OIL BLEND FOR DEEP BREATHING

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

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

LIFT HERE TO CONTINUE TO READ IMPORTANT PRODUCT INFORMATION ON ALL OIL BLENDS

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

We support recycling. Please recycle where possible

SKU 22250001

FORTIFY antitussive (cough suppressant) oil blend rub

Drug Facts

Active ingredient

Menthol 2.7%

Purpose Antitussive (Cough Suppressant)

Uses Temporarily calms cough due to minor throat and bronchial irritation associated with a cold or inhaled irritants. Relieves the impulse to cough to help you rest.

Warnings

For external use only. Do not that by mouth or place in nostrils.

Flammable. Keep away from fire or flame

Do not use

- if epileptic
- with high blood pressure

Ask doctor before use if you have

- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- cough accompanied by excessive phlegm (mucus).

When using this product, do not

- **heat**
- **microwave**
- **use near an open flame**
- **add to hot water or any container where heating water. May cause splattering and result in burns.**

Stop use and ask a doctor if

- cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache. A persistent cough may be a sign of a serious condition.

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

- **See important warnings under 'When using this product'**
- Adults and children 12 years or older:
- rub on throat and chest in a thick layer
- cover with warm cloth if desired
- clothing should be loose about throat and chest to help vapors reach the nose and mouth

- use up to three times daily or as directed by a doctor
- Children under 12 years of age: ask a doctor.

Other information

Close container tightly and store at room temperature away from heat .

Inactive ingredients

Cinnamon oil, eucalyptus oil, melaleuca alternifolia (tea tree) leaf oil, pelargonium graveolens oil, peppermint oil, pine needle oil, rosmarinus officinalis (rosemary) leaf oil, and vitis vinifera (grape) seed oil.

Fortify antitussive (cough suppressant) oil blend rub

Apply to the following areas, as directed:

A - Throat

B - Chest

SWEET COMFORT antitussive (cough suppressant) oil blend rub

Drug Facts

Active ingredient

Menthol 2.76%

Purpose Antitussive (Cough Suppressant)

Uses Temporarily relieves cough due to minor throat and bronchial irritation associated with the common cold or inhaled irritants. Suppresses your cough to help you get to sleep.

Warnings

For external use only. Do not take by mouth or place in nostrils.

Flammable. Keep away from fire or flame.

Ask doctor before use if you have

- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- cough accompanied by excessive phlegm (mucus)
- epilepsy

When using this product, do not

- heat
- microwave
- use near an open flame
- add to hot water or any container where heating water. May cause splattering and result in burns.
- sun tan/use tanning beds for 3-4 days after use

Stop use and ask a doctor if

cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache. A persistent cough may be a sign of a serious condition

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

- **See important warnings under 'When using this product'**
- Adults and children 12 years and older:
- rub on the throat and chest in a thick layer
- cover with a warm, dry cloth if desired
- clothing should be loose about throat and chest to help vapors reach the nose and mouth
- use up to three times daily or as directed by a doctor.

- Children under 12 years of age: ask a doctor.

Other information

- Close container tightly and store at room temperature away from heat.

Inactive ingredients

Benzoin, lavender oil, lemon oil, melaleuca alternifolia (tea tree) leaf oil, olibanum, peppermint oil, pine needle oil, and prunus armeniaca (apricot) kernel oil

Sweet Comfort antitussive (cough suppressant) oil blend rub

Apply to the following areas, as directed:

A - Throat

B - Chest

SOOTHING OIL BLEND

INHALE soothing oil blend for deep breathing

Directions for use: Used in aromatherapy to promote peaceful breaths. Apply to forehead and sinus areas, avoiding eyes and mucous membranes. Use on skin to soothe dry areas or add 10-20 drops to a bath. For prolonged use, consult a doctor.

Ingredients: Vitis vinifera (grape) seed oil, lavandula angustifolia (lavender) oil, citrus limon (lemon) peel oil, pelargonium graveolens oil, commiphora myrrha oil, mentha piperita (peppermint) oil, and anthemis nobilis flower oil .

Warnings: Keep out of reach of children. For external use only. if swallowed, seek urgent care/call poison control. If epileptic, consult a doctor before use. Avoid eyes & mucous membranes; if contact occurs, rinse with vegetable oil. Do not use if pregnant/breastfeeding. If allergic reaction occurs, stop use & consult a doctor. Phototoxic; do not sun tan/use tanning beds for 3-4 days after use.

Apply to the following areas:

A - Forehead

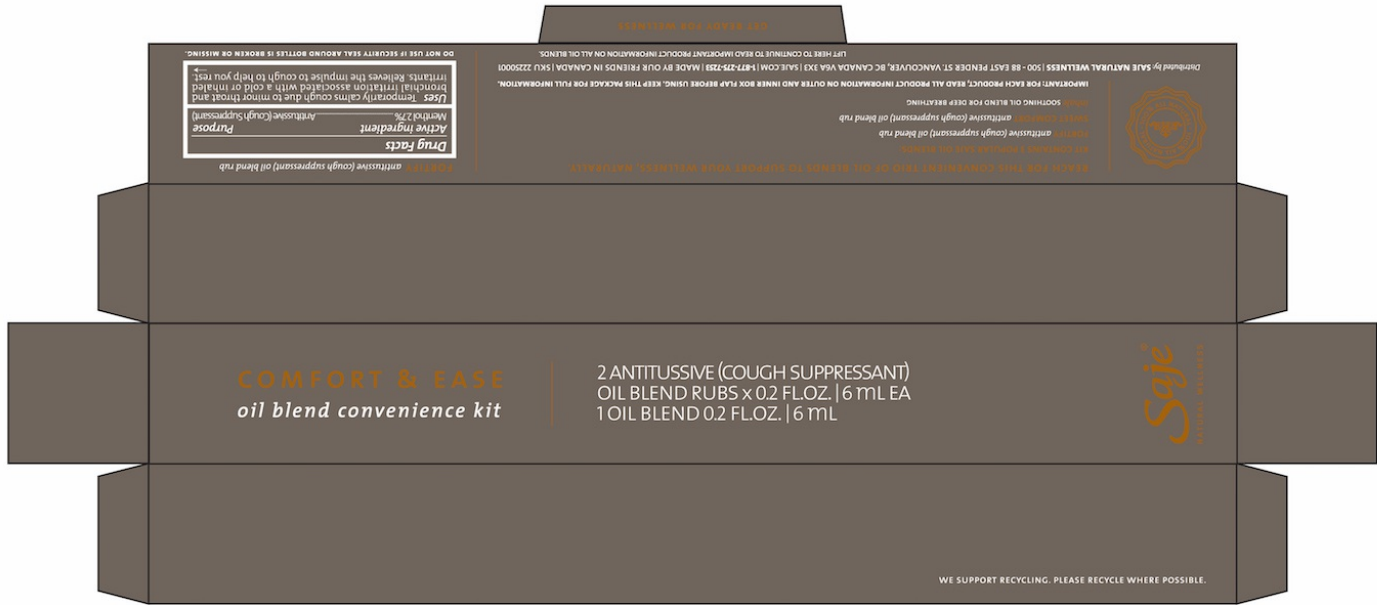
B - Sinus Area

COMFORT & EASE oil blend convenience kit



2 ANTITUSSIVE (COUGH SUPPRESSANT) OIL BLEND RUBS X 0.2 FL. OZ. | 6 mL EA

1 OIL BLEND 0.2 FL. OZ. | 6 mL

Saje® Natural Wellness



<p>FORTIFY (CONTINUED) antitussive (cough suppressant) oil blend rub</p> <p>Drug Facts (continued)</p> <p>Warnings For external use only. Do not take by mouth or place in nostrils. Flammable: Keep away from fire or flame. Do not use • if epileptic • with high blood pressure</p> <p>Ask a doctor before use if you have • persistent or chronic cough such as occurs with smoking, asthma, or emphysema • cough accompanied by excessive phlegm (mucus). When using this product, do not • heat • microwave • use near an open flame • add to hot water or any container where heating water. May cause splattering and result in burns. Stop use and ask a doctor if cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache. A persistent cough may be a sign of a serious condition.</p>	<p>Drug Facts (continued)</p> <p>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.</p> <p>Directions • See important warnings under "When using this product" • Adults and children 12 years and older • rub on the throat and chest in a thick layer • cover with a warm, dry cloth if desired • clothing should be loose about throat and chest to help vapors reach the nose and mouth • use up to three times daily or as directed by a doctor • Children under 12 years of age: ask a doctor.</p> <p>Other Information Close container tightly and store at room temperature away from heat.</p> <p>Inactive Ingredients Cinnamon oil, eucalyptus oil, melaleuca alternifolia (tea tree) leaf oil, pelargonium graveolens oil, peppermint oil, pine needle oil, rosmarinus officinalis (rosemary) leaf oil, and vitis vinifera (grape) seed oil.</p>	<p>FORTIFY antitussive (cough suppressant) oil blend rub</p> <p>APPLY TO THE FOLLOWING AREAS, AS DIRECTED: A - THROAT B - CHEST</p> 	<p>SWEET COMFORT antitussive (cough suppressant) oil blend rub</p> <p>Drug Facts</p> <p>Active ingredient Menthol 2.76% Purpose Antitussive (Cough Suppressant)</p> <p>Uses Temporarily relieves cough due to minor throat and bronchial irritation associated with the common cold or inhaled irritants. Suppresses your cough to help you get to sleep.</p> <p>Warnings For external use only. Do not take by mouth or place in nostrils. Flammable: Keep away from fire or flame. Ask a doctor before use if you have • persistent or chronic cough such as occurs with smoking, asthma, or emphysema • cough accompanied by excessive phlegm (mucus) • epilepsy. When using this product, do not • heat • microwave • use near an open flame • add to hot water or any container where heating water. May cause splattering and result in burns. • sun tan/use tanning beds for 3-4 days after use.</p>
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<p>SWEET COMFORT (CONTINUED) antitussive (cough suppressant) oil blend rub</p> <p>Drug Facts (continued)</p> <p>Stop use and ask a doctor if cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache. A persistent cough may be a sign of a serious condition. If pregnant or breast-feeding, do not use this product.</p> <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 • See important warnings under "When using this product" • Adults and children 12 years and older • rub on the throat and chest in a thick layer • cover with a warm, dry cloth if desired • clothing should be loose about throat and chest to help vapors reach the nose and mouth • use up to three times daily or as directed by a doctor • Children under 12 years of age: ask a doctor.</p>	<p>Drug Facts (continued)</p> <p>Other Information Close container tightly and store at room temperature away from heat.</p> <p>Inactive Ingredients Benzoin, lavender oil, lemon oil, melaleuca alternifolia (tea tree) leaf oil, oil of birch, peppermint oil, pine needle oil, and prunus armeniaca (apricot) kernel oil.</p> <p>SWEET COMFORT antitussive (cough suppressant) oil blend rub</p> <p>APPLY TO THE FOLLOWING AREAS, AS DIRECTED: A - THROAT B - CHEST</p> 	<p>SOOTHING OIL BLEND</p> <p>INHALE soothing oil blend for deep breathing</p> <p>DIRECTIONS FOR USE: USED IN AROMATHERAPY TO PROMOTE PEACEFUL BREATHS. APPLY TO FOREHEAD AND SINUS AREAS, AVOIDING EYES AND MUCOUS MEMBRANES. USE ON SKIN TO SOOTHE DRY AREAS OR ADD 10-20 DROPS TO A BATH. FOR PROLONGED USE, CONSULT A DOCTOR.</p> <p>INGREDIENTS: VITIS VINIFERA (GRAPE) SEED OIL, LAVANDULA ANGUSTIFOLIA (LAVENDER) OIL, CITRUS LIMON (LEMON) PEEL OIL, PELARGONIUM GRAVEOLENS OIL, COMMIPHORA MYRRHA OIL, MENTHA PIPERITA (PEPPERMINT) OIL, AND ANTHEMIS NOBILIS FLOWER OIL.</p> <p>WARNINGS: KEEP OUT OF REACH OF CHILDREN. FOR EXTERNAL USE ONLY. IF SWALLOWED, SEEK URGENT CARE/CALL POISON CONTROL. IF EPILEPTIC, CONSULT A DOCTOR BEFORE USE. AVOID EYES & MUCOUS MEM-</p>	<p>INHALE (CONTINUED) BRANES; IF CONTACT OCCURS, RINSE WITH VEGETABLE OIL. DO NOT USE IF PREGNANT/BREASTFEEDING. IF ALLERGIC REACTION OCCURS, STOP USE & CONSULT A DOCTOR. PHOTOTOXIC; DO NOT SUN TAN/USE TANNING BEDS FOR 3-4 DAYS AFTER USE.</p> <p>APPLY TO THE FOLLOWING AREAS: A - FOREHEAD B - SINUS AREA</p> 
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COMFORT AND EASE

menthol kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69204-017
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69204-017-18	1 in 1 KIT	10/16/2016	

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

Part 1 of 3

FORTIFY

menthol oil

Product Information

Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	24.03 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CINNAMON OIL (UNII: E5GY4I6YCZ)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
TEA TREE OIL (UNII: VIF565UC2G)	
PELARGONIUM GRAVEOLENS FLOWER OIL (UNII: 3K0J1S7QGC)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
PINE NEEDLE OIL (PINUS SYLVESTRIS) (UNII: 5EXL5H740Y)	
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		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 final	part341	10/16/2016	

Part 2 of 3

SWEET COMFORT

menthol oil

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	24.56 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
STYRAX BENZOIN RESIN (UNII: FE663Z8IRO)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
LEMON OIL (UNII: I9GRO824LL)	
TEA TREE OIL (UNII: VIF565UC2G)	
FRANKINCENSE OIL (UNII: 67ZYA5T02K)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
PINE NEEDLE OIL (PINUS SYLVESTRIS) (UNII: 5EXL5H740Y)	
APRICOT KERNEL OIL (UNII: 54JB35T06A)	

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		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 final	part341	10/16/2016	

Part 3 of 3

INHALE

other skin care preparations

Product Information

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	GRAPE SEED OIL (UNII: 930MLC8XGG)	
INGR	LAVENDER OIL (UNII: ZBP1YXW0H8)	
INGR	LEMON OIL (UNII: I9GRO824LL)	
INGR	PELARGONIUM GRAVEOLENS FLOWER OIL (UNII: 3K0J1S7QGC)	
INGR	MYRRH OIL (UNII: H74221J5J4)	
INGR	PEPPERMINT OIL (UNII: AV092KU4JH)	
INGR	CHAMAEMELUM NOBILE FLOWER OIL (UNII: UB27587839)	

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 final	part341	10/16/2016	

Labeler - Natures Formulae Health Products Ltd. (241385587)

Establishment

Name	Address	ID/FEI	Business Operations
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Revised: 10/2016

Natures Formulae Health Products Ltd.