

FORTIFY- menthol 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.

Fortify Antitussive (Cough Suppressant) Oil Blend Rub (30 ml, 10 ml, 6 ml)

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

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 take by mouth or place in nostrils

Flammable: Keep away from fire or flame.

Do not use

- if epileptic
- with high blood pressure

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.

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 of age 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

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.

Questions?

1-877-275-7253

Distributed by: **SAJE NATURAL WELLNESS** 500-88 E. Pender St. Vancouver, BC Canada V6A 3X3 | saje.com | **1-877-275-7253** | Made in Canada

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

Fortify 30 ml

SKU 332001

Fortify 10 ml

SKU 431301

Fortify 6 ml

LIFT HERE

SKU 439901

We support recycling. Please recycle where possible.

Fortify Antitussive (Cough Suppressant) Oil Blend Rub - 30 ml

Saje® Natural Wellness

Fortify

Antitussive (Cough Suppressant) Oil Blend Rub

For external use only.

1 fl. oz. | 30 ml



Fortify Antitussive (Cough Suppressant) Oil Blend Rub - 10 ml

fortify

Saje® Natural Wellness

Fortify

Antitussive (Cough Suppressant) Oil Blend Rub

For external use only.

0.34 fl. oz. | 10 ml

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

Drug Facts

Active ingredient	Purpose
Menthol 2.7%.....	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 take by mouth or place in nostrils.
Flammable: Keep away from fire or flame.
Do not use • if epileptic • with high blood pressure.
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.
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 of age 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 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.

Distributed by: SAJE NATURAL WELLNESS | 500-88 E. PENDER ST. VANCOUVER, BC CANADA V6A 3X3 | SAJE.COM | 1-877-275-7253 | MADE IN CANADA
DO NOT USE IF SECURITY SEAL AROUND BOTTLE IS BROKEN OR MISSING.
WE SUPPORT RECYCLING. PLEASE RECYCLE WHERE POSSIBLE.

SKU 431301

fortify

Saje®
NATURAL WELLNESS



fortify

antitussive (cough suppressant) oil blend rub

FOR EXTERNAL USE ONLY

0.34 fl.oz. | 10 ml

Fortify Antitussive (Cough Suppressant) Oil Blend Rub - 6 ml

fortify

Saje® Natural Wellness

Fortify

Antitussive (Cough Suppressant) Oil Blend Rub

For external use only.

0.2 fl. oz. | 6 ml

fortify

fortify

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

Drug Facts (continued)
 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 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.

Questions? 1-877-275-7253

Saje®
NATURAL WELLNESS



fortify
antitussive (cough suppressant) oil blend rub
FOR EXTERNAL USE ONLY

0.2 fl.oz. | 6 ml

Distributed by SAJE NATURAL WELLNESS 500-88 E. PENDER ST. VANCOUVER, B.C. CANADA V6A 3X3 | SAJE.COM | 1-877-275-7253 | MADE IN CANADA. DO NOT USE IF SECURITY SEAL AROUND BOTTLE IS BROKEN OR MISSING. WE SUPPORT RECYCLING. PLEASE RECYCLE WHERE POSSIBLE.

SKU 439901

Drug Facts

Active ingredient	Purpose
Menthol 2.7%	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 take by mouth or place in nostrils.
 Flammable: Keep away from fire or flame.
 Do not use • if epileptic • with high blood pressure.

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.

100% natural

Drug Facts (continued)

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 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.

Questions? 1-877-275-7253

FORTIFY

menthol oil

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69204-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	24 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	NDC:69204-003-03	1 in 1 BOX	10/16/2016	
1		30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
2	NDC:69204-003-04	1 in 1 BOX	10/16/2016	
2		10 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
3	NDC:69204-003-05	1 in 1 BOX	10/16/2016	
3		6 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

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
Natures Formulae Health Products Ltd.		241385587	manufacture(69204-003)

Revised: 10/2016

Natures Formulae Health Products Ltd.