SWEET COMFORT- 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.

Sweet Comfort Antitussive (Cough Suppressant) Oil Blend Rub (10 ml, 6 ml)

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

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. Supresses 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 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.

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

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

Sweet Comfort 10 ml

SKU 431701

Sweet Comfort 6 ml

Lift Here

SKU 432301

We support recycling. Please recycle where possible.

Sweet Comfort Antitussive (Cough Suppressant) Oil Blend Rub - 10 ml

sweet comfort

Saje® Natural Wellness

Sweet Comfort

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. sweet comfort Drug Facts Active ingredient Purpose Menthol 2.76% . 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 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. NATURAL WELLNESS 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. Stopuse and ask a doctorif cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent head-ache. 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 sweet comfort 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. antitussive (cough suppressant) oil blend rub Other Information Close container tightly and store at room temperature away from heat. Inactive ingredients Benzoin, lavender oil, lemon oil, mela-FOR EXTERNAL USE ONLY leuca alternifolia (tea tree) leaf oil, olibanum, peppermint oil, pine needle oil, and prunus armeniaca (apricot) kernel 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. 0.34fl.oz. | 10ml WE SUPPORT RECYCLING. PLEASE RECYCLE WHERE POSSIBLE. SKU 431701

Sweet Comfort Antitussive (Cough Suppressant) Oil Blend Rub - 6 ml

sweet comfort

Saje® Natural Wellness

Sweet Comfort

Antitussive (Cough Suppressant) Oil Blend Rub

For external use only.

0.2 fl. oz. | 6 ml



Drug Facts Active ingredient
Menthol 276% Artitussive (Cough Suppressant)
Uses Temporarily relieves cough due to minor throat and
bronchial mitation associated with the common cold or inhaled mitarits Suppresses your cough to helpyou 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 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. Stop use and ask a doctor if cough persists for more than I week, tends to recur, or is accompanied by fever, rash, or persistent headache. A persistent cough may be a sign of a serious condition.

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.

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Directions - See important warnings under When using this product - Adults and children 12 years and olders - rub on the throat and chest in a thick layer of cover with a warm, dy old hif desired - clothing should be loose about throat and chest to help supors reach the noise 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 alternifola (tea tree) leaf oil, olibanum, peppermint oil, pine needle oil, and prunus armeniaca (apricot) kernel oil.

Questions? 1-877-275-7253

SWEET COMFORT

menthol oil

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69204-004	
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 BENZO IN RESIN (UNII: FE663Z8IRO)		
LAVENDER O IL (UNII: ZBP1YXW0 H8)		
LEMON OIL (UNII: 19 GRO 8 2 4 L L)		
TEA TREE OIL (UNII: VIF565UC2G)		
FRANKINCENSE O IL (UNII: 67ZYA5T02K)		
PINE NEEDLE OIL (PINUS SYLVESTRIS) (UNII: 5EXL5H740 Y)		
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	NDC:69204-004- 04	1 in 1 BOX	10/16/2016	
1		10 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
2	NDC:69204-004- 05	1 in 1 BOX	10/16/2016	
2		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(69204-004)	

Revised: 10/2016 Natures Formulae Health Products Ltd.