

**BREATHIEZZZ- camphor,menthol oil
Fortunique B.V.**

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.

Drug Facts

Active Ingredients

Camphor 5%

Menthol 2.75%

Purpose

Cough Suppressant/Topical Analgesic

Uses

On chest and throat, temporarily relieves cough due to common cold

On muscles and joints, temporarily relieves minor aches and pains

Warning

For external use only

Avoid contact with eyes

Do not use

By mouth. With tight bandages

In nostrils. On wounds or damaged skin

Ask a Doctor before use if you have

Cough that occurs with too much phlegm(mucus). Persistent or chronic cough such as occurs within smoking, asthma or emphysema

When using this product, do not

Heat. Microwave. Add to hot water or any container where heating water. May cause splattering and result in burns

Stop use and ask a Doctor if

Muscle aches and pains persist more than 7 days or come back. Cough lasts more than 7 days, comes back occurs with fever, rash or persistent headache .

These could be signs of a serious condition

If pregnant or breast-feeding

Ask a health professional before use.

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away

Directions

See important warnings under " When using this product"

Adults and children 2 years and over: roll layer on chest & throat or roll on sore aching muscles. Cover with a warm, dry cloth if desired. Keep clothing loose around throat /chest to help vapors reach the nose/mouth. Repeat up to three times per 24 hours or as directed by doctor. Children under 2 years: do not use

Other information

Store at room temperature below 77° F

No added coloring agent and fragrance

Paraben and preservative free

Inactive Ingredients

Caprylic/Capric Triglycerides

Eucalyptol

Principle Display Panel. 10ml tube with applicator. Carton

Breathiezz helps you rest by temporarily relieving cough. Breathiezz contains Menthol and Camphor. Breathiezz comes in a convenient roll-on applicator for your toddler that has a temporary soothing and calming effect for coughs due to minor bronchial irritation associated with a common cold.

The practical roll-on applicator is fast, simple, efficient and hygienic in use and is specifically designed to apply a dosed, effective layer onto the skin of the chest with one movement.

The roller is easy to handle, convenient on-the-go and can be used with one hand. So you never have to lose contact with your toddler while caring for her/him.

Drug Facts (continued)

Directions
See important warnings under "When using this product"
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• Children under 2 years: do not use.

Other Information
Store at room temperature below 77°F.
No added coloring agents and fragrance.
Paraben and preservative free.

Inactive Ingredients
Caprylic/capric triglyceride, Eucalyptol.

Manufactured by:
ForTunique B.V.,
Lindenlaan 31C,
6584 AC Molenhoek (LB),
The Netherlands
www.fortunique.com

Distributed by:
Nutritional Products
International, Boca Raton, FL
Questions? Call 561-544-0719.

Made in The Netherlands
See package insert.
Breathiezz is a product of the
ForteCare range
of products.



Breathiezz

breathe
easy
roll-on

Breathiezz

breathe
easy
roll-on

Relieves your cough
to help you rest

Cough Suppressant/
Topical Analgesic

Net.Wt. 0.34 fl. oz. (10mL)

Drug Facts

Active Ingredient	Purpose
Camphor 5%	Cough Suppressant/ Topical Analgesic
Menthol 2.75%	Cough Suppressant/ Topical analgesic

Uses
• On chest and throat, temporarily relieves cough due to common cold
• On muscles and joints, temporarily relieves minor aches and pains

Warnings
• For external use only;
Avoid contact with eyes.

DO NOT USE
• By mouth • With tight bandages
• In nostrils • On wounds or damaged skin.

Ask a doctor before use if you have
• Cough that occurs with too much phlegm (mucus) • Persistent or chronic cough such as occurs with smoking, asthma or emphysema.

When using this product, do not
• Heat • Microwave • Add to hot water or any container where heating water. May cause splattering and result in burns.

Stop use and ask a doctor if:
• Muscle aches and pains persist more than 7 days or come back • Cough lasts more than 7 days, comes back or occurs with fever, rash or persistent headache. These could be signs of a serious condition.

If pregnant or breast-feeding,
ask a health professional before use.
Keep out of reach of children.
If swallowed, get medical help or contact a Poison Control Center right away.



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Batch no:

Exp. date:

BREATHIEZZ

camphor,menthol oil

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70359-4107
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	5 g in 100 g
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	2.75 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
EUCALYPTOL (UNII: RV6J6604TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70359-4107-1	1 in 1 CARTON	01/21/2016	
1		10 g in 1 TUBE, 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 final	part341	01/21/2016	

Labeler - Fortunique B.V. (407788616)

Registrant - Fortunique B.V. (407788616)

Establishment

Name	Address	ID/FEI	Business Operations
Fortunique B.V.		407788616	manufacture(70359-4107)

Revised: 12/2016

Fortunique B.V.