

KALAYA BREATHE EASY VAPORIZING RUB- vaporizing rub ointment

Avaria Health & Beauty Corp

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.

Kalaya Breathe Easy Ointment

Vaporizing Rub

DRUG FACTS	
Active Ingredients	Purpose
Camphor 4.8%	Cough Suppressant
Eucalyptus Oil 1.2%	Cough Suppressant
Menthol 2.6%	Cough Suppressant

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

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

If pregnant or breast-feeding, ask a health professional before use. **Keep out of the 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: • For cough suppression
 • Rub a thick layer on throat & chest • Cover with a warm, dry cloth if desired • Keep clothing loose about throat and chest to help vapors reach the nose and mouth

- Use up to three times daily or as directed by doctor
- Children under 2 years: do not use

Other Information

- Store at room temperature
- For your protection, do not use if the shrink seal is broken or missing

Inactive Ingredients

Beeswax, C15-23 Alkane, Hydrogenated Soy Polyglycerides, Hydrogenated Soybean Oil, Peppermint Oil

Questions or Comments?

Call toll-free 1.888.829.7165

A Synergistic Blend of Science & Nature

Inactive Ingredients
Beeswax, C15-23 Alkane, Hydrogenated Soy Polyglycerides, Hydrogenated Soybean Oil, Peppermint Oil

Purpose
.....Cough Suppressant
.....Cough Suppressant
.....Cough Suppressant

Uses
• on chest and throat, temporarily relieves cough due to minor throat and bronchial irritation associated with the common cold

Warnings

For external use only; avoid contact with eyes

Do not use • by mouth • in nostrils • on wounds or damaged skin • with tight bandages

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

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



KALAYA BREATHE EASY VAPORIZING RUB

vaporizing rub ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43493-0004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	26 g in 100 g
CAMPHOR (NATURAL) (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941)	CAMPHOR (NATURAL)	48 g in 100 g
EUCALYPTUS OIL (UNII: 2B040N1662) (EUCALYPTUS OIL - UNII:2B040N1662)	EUCALYPTUS OIL	12 g

EUCALYPTUS OIL (UNII: ZR040N100Z) (EUCALYPTUS OIL - UNII:ZR040N100Z)	EUCALYPTUS OIL	in 100 g
--	----------------	----------

Inactive Ingredients

Ingredient Name	Strength
C15-23 ALKANE (UNII: J3N6X3YK96)	
HYDROGENATED SOYBEAN OIL (UNII: A2M91M918C)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
WHITE WAX (UNII: 7G1J5DA97F)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43493-0004-1	1 in 1 BOX	11/16/2018	
1		60 g in 1 JAR; 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	11/16/2018	

Labeler - Avaria Health & Beauty Corp (251366043)

Revised: 12/2022

Avaria Health & Beauty Corp