

VAPORX BALM- camphor, eucalyptus oil, menthol ointment

Geritrex LLC

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.

Vaporx Balm

☐Active Ingredients:

Camphor 4.8%

Eucalyptus Oil 1.2%

Menthol 2.6%

☐Purpose:

Camphor - Cough Suppressant and Topical Analgesic

Eucalyptus Oil- Cough Suppressant

Menthol- Cough Suppressant and 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 - damaged skin or open wounds

☐Ask your doctor before use if you have:

- Persistent or chronic cough such as occurs with smoking, asthma or emphysema. - If excessive mucous present

☐When using this product, do not:

- heat - microwave - add to hot water or any container with heating water.

May cause splattering and result in burns

☐Stop use and ask doctor if:

- muscle aches and pains persists more than 7 days

- 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

Directions:

- Adults and children 2 years and over
- Rub a thick layer on chest & throat or rub on sore aching muscles
- Cover with warm, dry cloth if desired.
- Keep clothing loose around throat/chest to help vapors reach the nose and mouth
- repeat up to three times per 24 hours or as directed by doctor

Other Information: Store at room temperature

Inactive Ingredients:

nutmeg oil, modified petrolatum, thymol, turpentine oil

Questions? 1-800-736-3437



Vaporix Balm

Cough Relief
Muscle Ache Relief
Topical Analgesic

NET WT. 1.76 OZ (50g)

NDC#54162-450-50

Drug Facts

Active Ingredients	Purpose
Camphor 4.2% ... Cough suppressant & topical analgesic	
Eucalyptus oil 1.2% ...	Cough suppressant
Menthol 2.2% ...	Cough suppressant & topical analgesic

Uses:

- To clear and soothe, temporarily relieves cough due to common cold.
- To soothe sore throat, temporarily relieves muscle aches and joint pain.

Warnings:

For external use only, and do not use in the eyes.

Do not use: • In children • With light therapy • In sensitive areas • After skin surgery or on a wound • After use of other topical products

Ask your doctor for the use if you have:

- Asthma or other chronic lung disease • Allergy to any of the ingredients • If you are pregnant or breastfeeding

When using this product, do not:

- Use • Excessive use may irritate the skin.
- Use on open wounds or on the face.
- Use on children under the age of 2.
- Use on children under the age of 2, cause back, or neck or throat pain, or headache.
- Use on children under the age of 2, cause dizziness.

If pregnant or breast-feeding, ask a health care provider before use.

If you are using this product on a child, if weakness, get medical help at once or call a Poison Control center.

Directions:

- Rub a small amount on 2-3 times a day.
- Rub a thick layer on chest & throat several times a day.
- Cover with a clean, dry cloth if desired.
- Keep clothing loose and do not cover a body part more than 15 minutes.
- Avoid use on face.
- Avoid use if there have been 24 hours or longer of fever.

Other Information: • A cool, moist compress.

Inactive Ingredients: • Sesame oil, menthol, and other natural oils, to perfume.

Questions? 1-800-736-3437

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VAPORX BALM

camphor, eucalyptus oil, menthol ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54162-450
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	2.4 g in 50 g
EUCALYPTUS OIL (UNII: 2R04ONI662) (EUCALYPTUS OIL - UNII:2R04ONI662)	EUCALYPTUS OIL	0.6 g in 50 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1.3 g in 50 g

Inactive Ingredients

Ingredient Name	Strength
NUTMEG OIL (UNII: Z1CLM48948)	
PETROLATUM (UNII: 4T6H12BN9U)	
THYMOL (UNII: 3J50XA376E)	
TURPENTINE OIL (UNII: C5H0QJ6V7F)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54162-450-50	50 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	12/29/2015	

Labeler - Geritrex LLC (112796248)

Establishment

Name	Address	ID/FEI	Business Operations
Geritrex LLC		112796248	manufacture(54162-450)