

ASSURED VAPORIZING CHEST RUB- menthol camphor eucalyptus oil gel

Royal Exports

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.

Assured Chest Rub

Active Ingredients

Camphor 4.7 % Eucalyptus Oil 1% Menthol 2%

Purpose

Decongestant

Uses

- temporarily relieves nasal congestion, chest congestion, and cough due to the common cold
- temporarily relieves minor aches and pains

Warnings:

FOR EXTERNAL USE ONLY

When using this product

- Avoid contact with eyes
- Do not put into mouth, nostrils or on wounds or damaged skin

Consult a doctor before use if

- you are pregnant or breast feeding
- you have asthma, emphysema, persistent or chronic cough, cough associated with smoking or excessive mucus
- If mucus lasts more than 7 days, comes back or occurs with fever, rash or a persistent headache

Do not use near

- open flame
- microwave oven
- a container in which water is being heated except when adding cold water to a hot steam vaporizer

Keep out of reach of children

- If ingested, get medical help or contract a Poison Control Center right away

Directions

Adults and children 2 years of age and older

- rub thick layer on chest and throat for temporary relief from nasal congestion and coughing due to colds or rub on sore aching muscles
- If desired, cover with a soft dry cloth but keep clothing loose

- repeat up to three times daily especially at bedtime

Children under 2 years of age

- consult your physician

Inactive Ingredients

Petrolatum, Mineral Oil, Nutmeg Oil, Turpentine Oil, Thymol, Cedar Leaf Oil

PACKAGE LABEL



ASSURED VAPORIZING CHEST RUB

menthol camphor eucalyptus oil gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51328-2060
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	5.3 g in 113 g
EUCALYPTUS OIL (UNII: 2R04ONI662) (EUCALYPTUS OIL - UNII:2R04ONI662)	EUCALYPTUS OIL	1.13 g in 113 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	2.26 g in 113 g

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	
MINERAL OIL (UNII: T5L8T28FGP)	
NUTMEG OIL (UNII: Z1CLM48948)	
TURPENTINE OIL (UNII: C5H0QJ6V7F)	
THYMOL (UNII: 3J50XA376E)	
CEDAR LEAF OIL (UNII: BJ169U4NLG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51328-2060-1	113 g in 1 JAR; Type 0: Not a Combination Product	03/21/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/21/2019	

Labeler - Royal Exports (650621381)

Revised: 3/2019

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