

**ASSURED VAPORIZING CHEST RUB- camphor and eucalyptus oil and menthol ointment
Greenbrier International, Inc.**

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.

Active Ingredients

Camphor 4.7%
Eucalyptus Oil 1.2%
Menthol 1.25%

Purpose

Cough Suppressant & Topical analgesic
Cough Suppressant
Cough Suppressant & Topical analgesic

Uses

- use on chest and throat to temporarily relieve cough
- use on aching muscles to temporarily relieve minor aches and pains

Warnings

For external use only; Do not take by mouth or place in nostrils. Avoid excessive heat. Never expose this product to flame or place in any container in which you are heating water. Never place in microwave oven.

Consult a doctor and discontinue use;

If cough persist for more than 1 week, tends to recur or is accompanied by fever, rash or persistent headache.

Keep out of reach of children

In case of accidental ingestion, seek professional assistance or contact a Poison Control Centre immediately.

Directions:

- Adults and children over 2 years of age; Rub a thick layer on chest and throat to provide temporary relief from nasal congestion and coughing due to colds. If desired, cover with dry, warm cloth, but keep clothing loose to let the vapours rise to nose and mouth. Repeat up to three times daily, especially at bedtime, or as directed by a doctor.
- Children under two years of age, consult a doctor.

Inactive Ingredients:

Petrolatum, Mineral Oil, Nutmeg Oil, Spirits of Turpentine, Cedarleaf Oil, Thymol

PRINCIPAL DISPLAY PANEL

ASSURED VAPORIZING CHEST RUB



ASSURED VAPORIZING CHEST RUB				
camphor and eucalyptus oil and menthol ointment				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:33992-7992	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
CAMPBOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPBOR (SYNTHETIC) - UNII:5TJD82A1ET)		CAMPBOR (SYNTHETIC)	4.7 g in 100 g	
EUCALYPTUS OIL (UNII: 2R04ONI662) (EUCALYPTUS OIL - UNII:2R04ONI662)		EUCALYPTUS OIL	1.2 g in 100 g	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)		MENTHOL	1.25 g in 100 g	
Inactive Ingredients				
Ingredient Name			Strength	
PETROLATUM (UNII: 4T6H12BN9U)				
MINERAL OIL (UNII: T5L8T28FGP)				
NUTMEG OIL (UNII: Z1CLM48948)				
TURPENTINE OIL (UNII: C5H0QJ6V7F)				
CEDAR LEAF OIL (UNII: BJ169U4NLG)				
THYMOL (UNII: 3J50XA376E)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:33992-7992-4	113 g in 1 JAR; Type 0: Not a Combination Product	01/18/2019	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	01/18/2019		

Labeler - Greenbrier International, Inc. (610322518)

Registrant - Jell Pharmaceuticals Pvt. Ltd. (726025211)

Establishment

Name	Address	ID/FEI	Business Operations
Jell Pharmaceuticals Pvt. Ltd.		726025211	manufacture(33992-7992)

Revised: 1/2019

Greenbrier International, Inc.