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%

Menthol 1.25%

Eucalyptus Oil 1.2%

Purpose

Cough suppressant/topical analgesic

Cough suppressant/topical analgesic

Cough suppressant

Uses

Temporarily relieves throat and chest

- cough
- nasal congestion due to common cold
- aching muscles
- minor aches and pains

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

- asthama
- excessive phlegm (mucus)
- emphysema
- persistent or chronic cough
- cough associated with smoking

When using this product do not

- heat
- microwave
- use near open flame
- 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/pain persist more than 7 days or come back
- cough lasts more than 7 days, comes back, or occurs with fever, rash or headache that lasts. These could be signs of a serious conditions.

If pregnant or breast feeding, ask a health professional before use.

Keep out of reach of children. In case of accidental ingestion, get medical help or contact a Poison Control Centre right away.

Directions

- see important warnings under "When using this product"
- children under 2 years of age, ask a doctor before using this product
- adults and children 2 years and older, rub a thick layer on chest and throat or rub on sore aching muscles. If desired, cover with a dry soft cloth but keep clothing loose. Repeat up to 3 times daily.

Other information

• Store at room temperature

Inactive ingredients

cedar leaf oil, nutmeg oil, paraffin, petrolatum, thymol, turpentine oil

PRINCIPAL DISPLAY PANEL

ASSURED VAPORIZING CHEST RUB



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camphor and eucalyptus oil and menthol ointment

| Product Information | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:33992-7991 |
| Route of Administration | TOPICAL | | |

| Active Ingredient/Active Moiety | | | | |
|--|------------------------|--------------------|--|--|
| Ingredient Name | Basis of Strength | Strength | | |
| CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET) | CAMPHOR (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 | | |

| ı | Inactive Ingredients | |
|---|----------------------|----------|
| | Ingredient Name | Strength |

| CEDAR LEAF OIL (UNII: BJ169U4NLG) | |
|-----------------------------------|--|
| NUTMEG OIL (UNII: Z1CLM48948) | |
| MINERAL OIL (UNII: T5L8T28FGP) | |
| PETRO LATUM (UNII: 4T6 H12BN9 U) | |
| THYMOL (UNII: 3J50XA376E) | |
| TURPENTINE OIL (UNII: C5H0QJ6V7F) | |

| l | Packaging | | | | |
|---|--------------------|---|----------------------|---------------------------|--|
| l | # Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| l | 1 NDC:33992-7991-4 | 113 g in 1 JAR; Type 0: Not a Combination Product | 06/26/2018 | | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph final | part341 | 06/26/2018 | |
| | | | |

Labeler - Greenbrier International, Inc. (610322518)

Registrant - Jell Pharmaceuticals Pvt. Ltd. (726025211)

| Establishment | | | | | |
|--------------------------------|---------|-----------|-------------------------|--|--|
| Name | Address | ID/FEI | Business Operations | | |
| Jell Pharmaceuticals Pvt. Ltd. | | 726025211 | manufacture(33992-7991) | | |

Revised: 1/2019 Greenbrier International, Inc.