

## **LEADER VAPOR STEAM CAMPHOR (SYNTHETIC)- camphor (synthetic) liquid CARDINAL HEALTH**

*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.*

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### **LEADER VAPOR STEAM (relisted)**

#### **Drug Facts**

##### **Active ingredient**

Camphor 6.2%

##### **Purpose**

Cough suppressant

##### **Use**

temporarily relieves cough occurring with a cold

##### **Warnings**

###### **For external use only.**

**Flammable:** Keep away from fire or flame.

For steam inhalation only.

###### **Ask a doctor before use if you have**

- a cough that lasts or is chronic such as occurs with smoking, asthma, or emphysema
- cough that occurs with too much phlegm (mucus)

###### **When using this product, do not**

- heat
- microwave
- use near an open flame
- take by mouth
- direct steam from the vaporizer too close to the face
- add to hot water or any container where heating water except when adding to cold water only in a hot steam vaporizer. May cause splattering and result in burns.

###### **Stop use and ask a doctor if**

cough lasts more than 7 days, comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition.

## **Keep out of reach of children.**

If swallowed, get medical help or contact a Poison Control Center right away. In case of eye exposure, flush with water.

## **If pregnant or breast-feeding,**

ask a health professional before use.

## **Directions**

- **see important warnings under "When using this product"**
- **adults & children 2 years & over:**
- use 1 tablespoon of solution for each quart of water or 1½ teaspoonful of solution for each pint of water
- add solution directly to cold water only in a hot steam vaporizer
- follow manufacturer's directions for using vaporizer
- breathe in the medicated vapors
- use up to three times daily or as directed by a doctor
- children under 2 years: ask a doctor

## **Other information**

close container tightly and store at room temperature away from heat

## **Inactive ingredients**

alcohol (78%), cedarleaf oil, dimethicone, eucalyptus oil, laureth-7, menthol, nutmeg oil, poloxamer 124

**Tamper-evident:** do not use if the imprinted seal under the cap is broken or missing.

**Keep this carton. It has important information.**

## **PRINCIPAL DISPLAY PANEL - 8oz**

CAUTION: NOT FOR INTERNAL USE

NDC 70000-0563-1

LEADER

Vapor Steam

Camphor, 6.2%

Cough Suppressant

Liquid Medication For Hot Steam Vaporizers


Temporarily Relieves Steam

Soothing Menthol Scent

Compare Vicks® Vapo Steam active ingredient\*

100% Money Back Guarantee

8 fl oz (237 mL)

|  |                     |                     |              |                      |                              |                         |
|--|---------------------|---------------------|--------------|----------------------|------------------------------|-------------------------|
| <br>IMPRESSIONS INCORPORATED<br>1050 Westgate Drive Saint Paul Minnesota 55114<br>T 800.251.4285 F 651.646.7228<br>E info@i.com W www.i.com | Job Code<br>387798  | Item Description    |              |                      |                              | Date<br>7/17/2020       |
|  | Item Code<br>159294 | Part Number<br>6679 | Other Number | CAD Number<br>18135A | Flat Size<br>10.094 x 11.094 | Print Process<br>Offset |
| Inks<br>Cyan Magenta Yellow Black 200 288 CAD Glue/No coat area  |                     |                     |              |                      |                              |                         |
| <b>NOTE TO OUR CUSTOMERS:</b><br>When viewing proof with Acrobat always activate "Overprint Preview"<br>Preferences / General / Page Display / Use Overprint Preview / Always  |                     |                     |              |                      |                              |                         |



**LEADER VAPOR STEAM CAMPHOR (SYNTHETIC)**  
 camphor (synthetic) liquid

## Product Information

|                                |                          |                           |                |
|--------------------------------|--------------------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN OTC DRUG           | <b>Item Code (Source)</b> | NDC:70000-0563 |
| <b>Route of Administration</b> | RESPIRATORY (INHALATION) |                           |                |

## Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength   | Strength        |
|---|---------------------|-----------------|
| <b>CAMPHOR (SYNTHETIC)</b> (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET) | CAMPHOR (SYNTHETIC) | 0.062 g in 1 mL |

## Inactive Ingredients

| Ingredient Name                          | Strength |
|--|----------|
| <b>NUTMEG OIL</b> (UNII: Z1CLM48948)     |          |
| <b>POLOXAMER 124</b> (UNII: 1S66E28KXA)  |          |
| <b>LAURETH-7</b> (UNII: Z95S6G8201)      |          |
| <b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)    |          |
| <b>MENTHOL</b> (UNII: L7T10EIP3A)        |          |
| <b>CEDAR LEAF OIL</b> (UNII: BJ169U4NLG) |          |
| <b>ALCOHOL</b> (UNII: 3K9958V90M)        |          |
| <b>EUCALYPTUS OIL</b> (UNII: 2R04ONI662) |          |

## Packaging

| # | Item Code        | Package Description  | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:70000-0563-1 | 1 in 1 CARTON  | 09/02/2020           |                    |
| 1 |                  | 237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product |                      |                    |

## Marketing Information

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | M012                                     | 09/02/2020           |                    |

**Labeler** - CARDINAL HEALTH (063997360)

**Registrant** - Weeks & Leo Co., Inc. (005290028)

## Establishment

| Name                  | Address | ID/FEI    | Business Operations     |
|-----------------------|---------|-----------|-------------------------|
| Weeks & Leo Co., Inc. |         | 005290028 | manufacture(70000-0563) |

