

WEEKS AND LEO MEDICATED VAPORIZING STEAM- camphor (synthetic) liquid
Weeks & Leo Co., 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.

W&L Medicated Vaporizing Steam Liquid

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.

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 - 4oz

CAUTION: NOT FOR INTERNAL USE

NDC 11383-256-04

WEEKS&LEO**Medicated VAPORIZING STEAM LIQUID**

Relieves Cough to Help You Rest

Liquid Medication For Hot Steam Vaporizers

Cough Suppressant

Contains Camphor

Compare Vicks ® Vapo Steam active ingredient*

4 fl oz (118 mL)

<small>CAUTION: NOT FOR INTERNAL USE</small> <small>NDC 11383-256-04</small>		Failure to follow these warnings could result in serious consequences.					
WEEKS & LEO		WEEKS & LEO					
Medicated VAPORIZING STEAM LIQUID Relieves Cough to Help You Rest Liquid Medication For Hot Steam Vaporizers Easy to use: <small>(See directions before use)</small> • Adds directly to cold water in any hot steam vaporizer. • Only one tablespoonful of Medicated Vaporizing Steam Liquid required for each quart of water used. <small>Compare to Vicks® Vapo Steam active ingredient*</small>		Medicated VAPORIZING STEAM LIQUID Relieves Cough to Help You Rest Liquid Medication For Hot Steam Vaporizers Cough Suppressant Contains Camphor  <small>Compare to Vicks® Vapo Steam active ingredient*</small> 4 fl oz (118 mL)					
		Drug Facts <table border="1"> <tr> <th>Active ingredient</th> <th>Purpose</th> </tr> <tr> <td>Camphor 6.2%</td> <td>Cough suppressant</td> </tr> </table>		Active ingredient	Purpose	Camphor 6.2%	Cough suppressant
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		Drug Facts (continued) Directions ■ see important warnings under "When using this product" ■ adults and children 2 years and older: ■ use 1 tablespoonful of solution for each quart of water or 1-1/2 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 of age: ask a doctor					
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		<small>* This product is not manufactured or distributed by Procter & Gamble, owner of the registered trademarks Vicks® Vapo Steam®.</small>					
		Tamper-evident: do not use if the imprinted seal under the cap is broken or missing.					
		Keep this carton. It has important information.					
		<small>Distributed By: Weeks & Leo Co., Inc. 4000 NW 100th St., Des Moines, IA 50322 www.weeksleo.com</small>					
		Made in USA 01-256-043.0					

WEEKS AND LEO MEDICATED VAPORIZING STEAM			
camphor (synthetic) liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11383-256
Route of Administration	RESPIRATORY (INHALATION)		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	0.623 g in 10 mL
Inactive Ingredients			
	Ingredient Name	Strength	
	ALCOHOL (UNII: 3K9958V90M)		
	CEDAR LEAF OIL (UNII: BJ169U4NLG)		
	EUCALYPTUS OIL (UNII: 2R040NI662)		
	LAURETH-7 (UNII: Z95S6G8201)		
	MENTHOL (UNII: L7T10EIP3A)		
	NUTMEG OIL (UNII: Z1CLM48948)		
	POLOXAMER 124 (UNII: 1S66E28KXA)		
	DIMETHICONE (UNII: 92RU3N3Y10)		

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11383-256-08	1 in 1 CARTON	07/01/2014	
1		236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:11383-256-04	1 in 1 CARTON	07/01/2014	
2		118 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	part341	11/02/2011	

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

Name	Address	ID/FEI	Business Operations
Weeks & Leo Co., Inc.		005290028	manufacture(11383-256)

Revised: 3/2017

Weeks & Leo Co., Inc.