VAPO STEAM- vapo steam liquid TOPCO ASSOCIATES, LLC

TopCare ® Health Vaporizing Steam Liquid 8 FL OZ (240 mL)

Drug Facts

Active ingredient

Camphor (Synthetic) 6.2%

Purpose

Cough suppressant

Uses

temporarily relieves cough due to minor throat and bronchial irritation associated 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 persistent or chronic cough 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
- 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 serious condition.

Keep out of reach of children.

In case of eye exposure (flush eyes with water); or in case of accidental igestion, seek medical help or contact a Poison Control Center right away.

Directions

- see important warnings under "When using this product"
- adults & children 2 years & over:

add 1 tablespoon of solution to each quart of water or $1\frac{1}{2}$ teaspoons of solution to 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: do not use

Other information

close container tightly and store at room temperature away from heat

Inactive ingredients

dimenthicone, eucalyptus globulus (eucalyptus oil) leaf oil, laureth-7, menthol, myristica fragrans (nutmeg) kernel oil, poloxamer 124, SD alcohol 40-B, thuja occidentalis (cedar leaf) oil

TopCare® Health Vaporizing Steam Liquid 8 FL OZ (240 mL) - Bottle Label





Product Type HUMAN OTC DRUG Item Code (Source) NDC:76162-030

Route of Administration RESPIRATORY (INHALATION)

Active Ingredient/Active Moiety

Active Ingredient/Active Molety		
Ingredient Name	Basis of Strength	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	6.2 g in 100 mL

Inactive Ingredients		
Ingredient Name Strength		
ALCOHOL (UNII: 3K9958V90M)		
EUCALYPTUS OIL (UNII: 2R040NI662)		
NUTMEG OIL (UNII: Z1CLM48948)		
DIMETHICONE (UNII: 92RU3N3Y1O)		
CEDAR LEAF OIL (UNII: BJ169U4NLG)		
MENTHOL (UNII: L7T10EIP3A)		
LAURETH-7 (UNII: Z95S6G8201)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76162-030- 08	1 in 1 CARTON	01/11/2024	
1	NDC:76162-030- 04			

Marketing In	Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M012	02/01/2023		

Labeler - TOPCO ASSOCIATES, LLC (006935977)

Registrant - Unipack LLC (009248480)

Establishment				
Name	Address	ID/FEI	Business Operations	
Unipack LLC		009248480	manufacture(76162-030)	