ENDACOF DM- brompheniramine maleate, dextromethorphan hydrobromide and phenylephrine hydrochloride liquid
Larken Laboratories, 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.

EndaCof DM

Drug Facts

Active Ingredients

(In each 5 mL teaspoonful)

Brompheniramine Maleate, USP 1 mg

Dextromethorphan HBr, USP 5 mg

Phenylephrine HCl, USP 2.5 mg

Purpose

Brompheniramine Maleate Antihistamine

Dextromethorphan HBr Antitussive (cough suppressant)

Phenylephrine HCl Nasal decongestant

Uses

Temporarily relieves these symptoms due to hay fever (allergic rhinitis):
- cough due to minor throat and bronchial irritation
- runny nose
- sneezing
- itchy, watery eyes
- itching of the nose or throat
- temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies
- temporarily restores freer breathing through the nose

Warnings

Do not use
- to sedate a child or make a child sleepy
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this drug.

Ask a doctor before use if you have
- heart disease
- high blood pressure

- thyroid disease
- diabetes
- glaucoma
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis
- a cough that lasts or is chronic such as occurs with smoking, asthma or emphysema
- a cough that occurs with too much phlegm (mucus)

Ask a doctor or pharmacist before use if you are
- taking any other nasal decongestant or stimulant
- taking sedatives or tranquilizers

When using this product

Do not exceed recommended dosage.
- marked drowsiness may occur
- avoid alcoholic beverages
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

Stop use and ask a doctor if
- nervousness, dizziness, or sleeplessness occur.
- cough or nasal congestion persists for more than 1 week, tends to recur, or is accompanied by a fever, rash or persistent headache. These could be signs of a serious condition.

If pregnant or breast-feeding

ask a health professional before use.

Keep out of the reach of children

In case of overdose, get medical help or contact a Poison Control Center immediately.

Directions

Do not exceed 6 doses in a 24-hour period

Age	Dose
Adults and children over 12 years of age:	4 teaspoonsful (20 mL) every 4 hours
Children 6 to under 12 years of age:	2 teaspoonsful (10 mL) every 4 hours
Children under 6 years of age:	Ask your doctor

Other Information
- store at 20°-25°C (68°-77°F)
- very low sodium, contains 1 mg sodium per teaspoonful (5 mL)

Inactive Ingredients

Benzoic acid, edetate disodium, FD&C Red #40, propylene glycol, purified water saccharin sodium,

sorbitol solution and strawberry flavoring

Questions or Comments

Call 1-888-527-5522 weekdays from 9:00 am to 4:00 pm CST or go to http://www.larkenlabs.com.

Principal Display Panel

Figure 1: 16 oz. Bottle Label

ENDACOF DM

brompheniramine maleate, dextromethorphan hydrobromide and phenylephrine hydrochloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68047-143
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

BROMPHENIRAMINE MALEATE (UNII: IXA7C9ZN03) (BROMPHENIRAMINE - UNII:H57G17P2FN)	BROMPHENIRAMINE MALEATE	1 mg in 5 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
BENZOIC ACID (UNII: 8SKN0B0MIM)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	red	**Score**	
Shape		**Size**	
Flavor	STRAWBERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68047-143-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/30/2012	

Labeler - Larken Laboratories, Inc. (149484540)

Registrant - Larken Laboratories, Inc. (149484540)

Revised: 11/2019 Larken Laboratories, Inc.