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

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

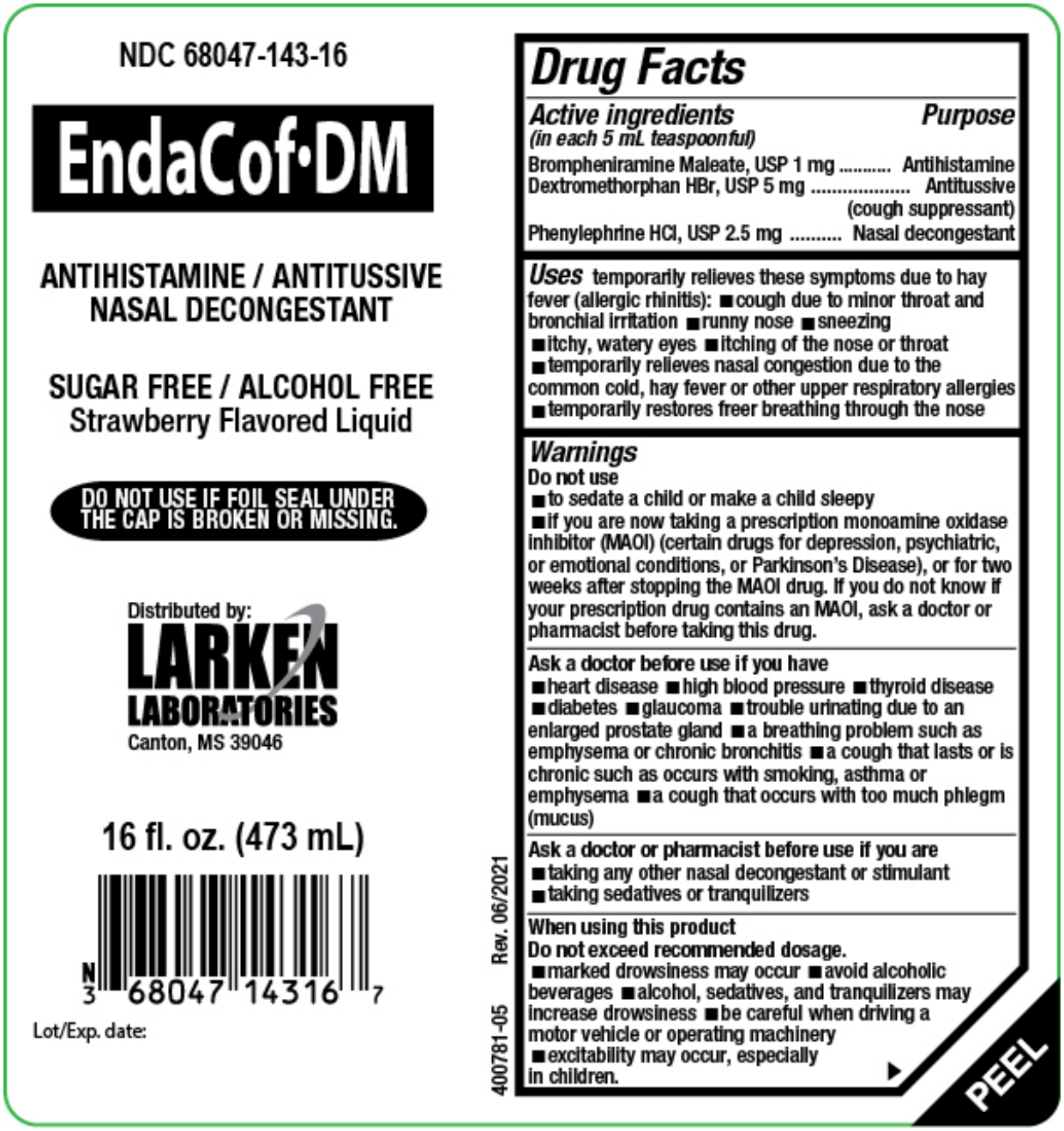
Benzoic acid, edetate disodium, FD&C Red #40, propylene glycol, purified water saccharin sodium, sorbitol solution and strawberry flavoring

Questions or Comments

Call 1-601-855-7678 weekdays from 9:00 am to 4:00 pm CST or go to http://www.larkenlabs.com.

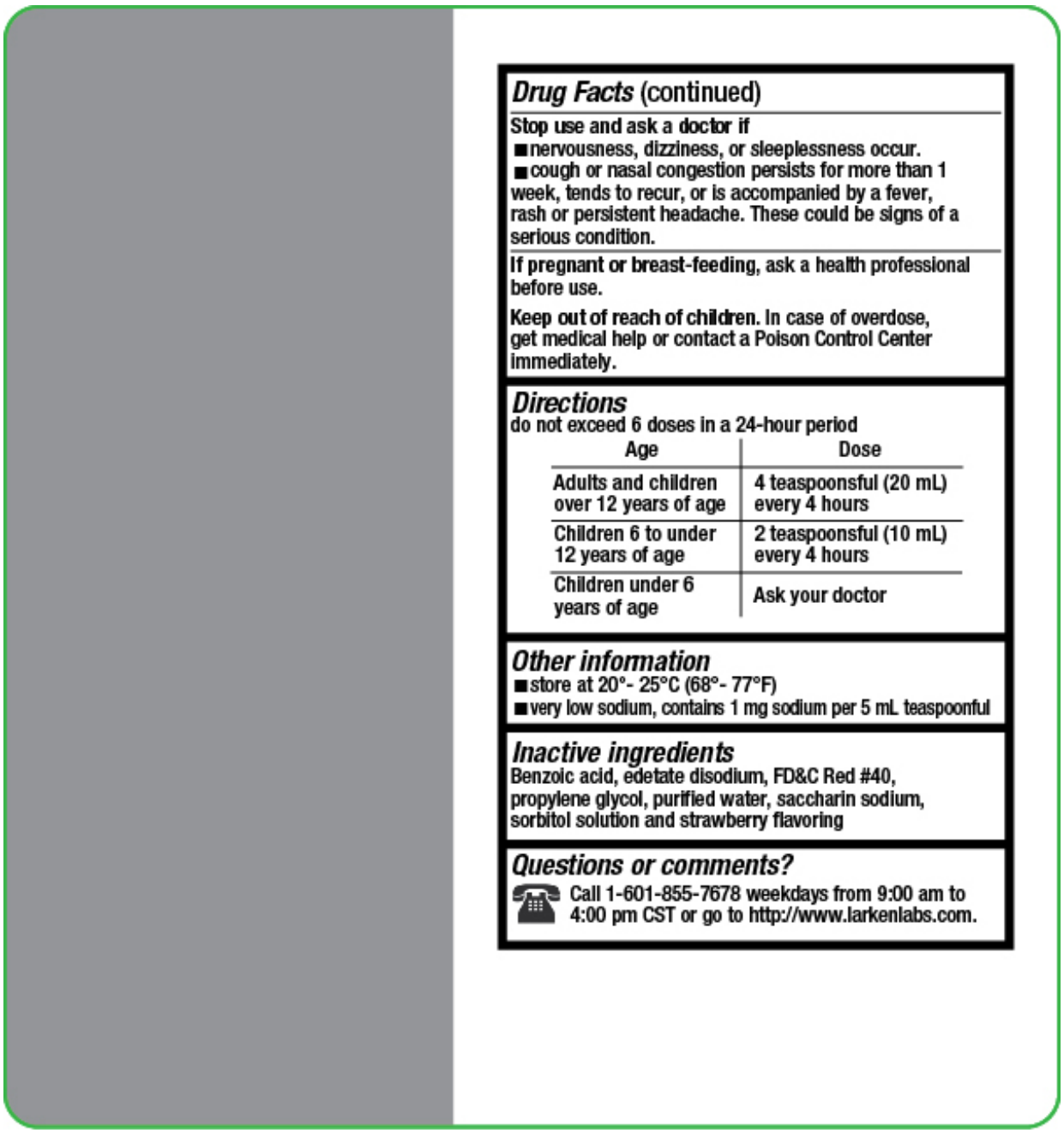
Principal Display Panel

Figure 1: 16 oz. Bottle Label (Front)



Principal Display Panel

Figure 2: 16 oz. Bottle Label (Drug Facts Continued)



Drug Facts (continued)

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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 Drug	M012	03/30/2012	

Labeler - Larken Laboratories, Inc. (149484540)

Revised: 10/2023 Larken Laboratories, Inc.