DEXBROMPHENIRAMINE-DM-PHENYLEPHRINE 2-15-7.5- dexbrompheniramine maleate, dextromethorphan hydrobromide and phenylephrine hydrochloride liquid
AddGen Pharmaceuticals, 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.

Active ingredients

(in each 5 mL teaspoonful)

Dexbrompheniramine Maleate 2 mg

Dextromethorphan Hydrobromide 15 mg

Phenylephrine Hydrochloride 7.5mg

Purpose

Antihistamine
Antitussive
Nasal Decongestant

Uses

temporarily relieves these symptoms due to the common cold, hay fever (allergic rhinitis) or other upper respiratory allergies:

- runny nose
- sneezing
- itching of nose or throat
- itchy, watery eyes
- cough due to minor throat and bronchial irritation
- nasal congestion
- reduces swelling of nasal passages

Warnings

Do not exceed recommended dosage.

Do not use

this product

- 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 product.

Ask a doctor before use

if you have

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

Ask a doctor or pharmacist before use

if you are

taking sedatives or tranquilizers.

When using this product

- excitability may occur, especially in children
- may cause marked drowsiness
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase the drowsiness effect
- be careful when driving a motor vehicle or operating machinery

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. A persistent cough may be a sign of a serious condition.
- new symptoms occur

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

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

Directions

Do not exceed recommended dosage.

Adults and children 12 years of age	1 teaspoonful (5 mL) every 4 to 6 hours, not to exceed 6 teaspoonfuls in a 24

and over:	teaspoonfuls in a 24 hours
Children 6 to under 12 years of age:	1/2 teaspoonful (2.5 mL) every 4 to 6 hours, not to exceed 3 teaspoonfuls in 24 hours
Children under 6 years of age:	Consult a doctor.

Other information

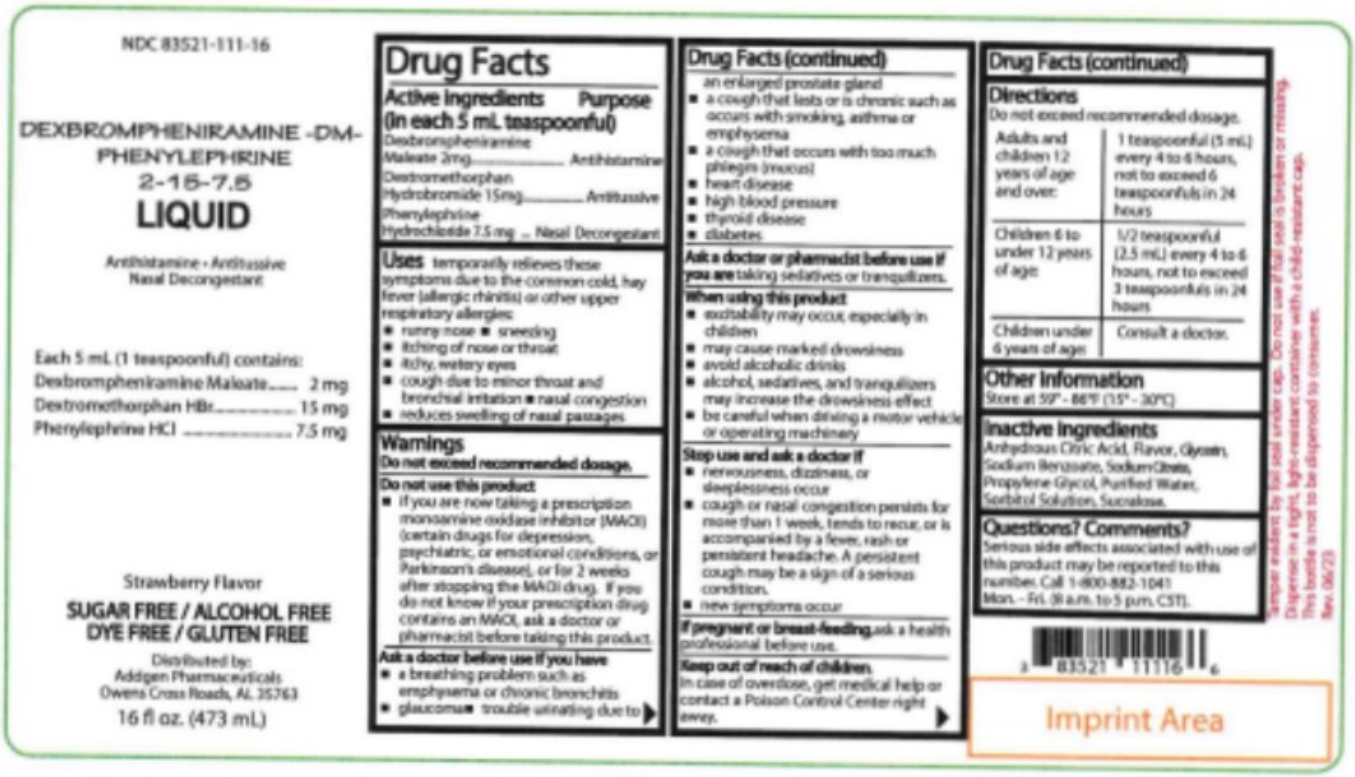
Store at 59° - 86°F (15° - 30°C)

Inactive ingredients

Anhydrous Citric Acid, Glycerin, Flavor, Propylene Glycol, Purified Water, Sodium Benzoate, Sodium Citrate Dihydrate, Sodium Saccharin, Sorbitol Solution.

Questions? Comments?

Serious side effects associated with use of this product may be reported to this number.
Call 1-800-882-1041
Mon. - Fri. (8 a.m. to 5 p.m. CST).



DEXBROMPHENIRAMINE-DM-PHENYLEPHRINE 2-15-7.5

dexbrompheniramine maleate, dextromethorphan hydrobromide and phenylephrine hydrochloride

liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:83521-111
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXBROMPHENIRAMINE MALEATE (UNII: BPA9UT29BS) (DEXBROMPHENIRAMINE - UNII:75T64B71RP)	DEXBROMPHENIRAMINE MALEATE	2 mg in 5 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	7.5 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83521-111-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/01/2023	

Labeler - AddGen Pharmaceuticals, Inc. (118994799)

Revised: 7/2023 AddGen Pharmaceuticals, Inc.