

DEXTROMETHORPHAN HYDROBROMIDE, GUAIFENESIN, AND PHENYLEPHRINE HYDROCHLORIDE- dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride liquid
Westminster Pharmaceuticals, LLC

DEXTROMETHORPHAN HYDROBROMIDE, GUAIFENESIN, AND PHENYLEPHRINE HYDROCHLORIDE

Drug Facts

<i>Active ingredients (in each 15 mL (TBSP))</i>	<i>Purpose</i>
Dextromethorphan HBr 18 mg	Cough Suppressant
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 10 mg	Nasal Decongestant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily relieves:
 - cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
 - the intensity of coughing
 - the impulse to cough to help you get to sleep
 - nasal congestion due to a cold

Warnings

Do Not Use 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

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- a cough that lasts or is chronic such as occurs with smoking, asthma, or emphysema
- a cough that occurs with too much phlegm (mucus)
- difficulty in urination due to enlargement of the prostate gland

When using this product do not use more than directed

Stop use and ask a doctor if

- nervousness, dizziness or sleeplessness occurs
- symptoms do not improve within 7 days or are 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 take more than 6 doses in any 24-hour period
- use enclosed dosage cup or tablespoon (TBSP)
- dose as follows or as directed by a doctor

Adults and children 12 years of age and over:	15 mL (1 TBSP) every 4 hours, not to exceed 90 mL (6 TBSP) in a 24 hour period
Children 6 to under 12 years of age:	7.5 mL (1/2 TBSP) every 4 hours, not to exceed 45 mL (3 TBSP) in a 24 hour period.
Children under 6 years of age:	Consult a doctor.

Other information

- Each 15 mL (TBSP) contains **Sodium 8 mg.**
- store at 68°-86°F (20°-30°C)

Inactive ingredients

citric acid anhydrous, glycerin, propylene glycol, purified water, raspberry flavor, sodium benzoate, sodium citrate dihydrate, sodium saccharin, sorbitol.

Questions or Comments?

- Call weekdays from 9 AM to 5 PM EST at 1-844-7294. You may also report serious side effects to this phone number.

PRINCIPAL DISPLAY PANEL - 240 mL Bottle Label

NDC 69367-184-08

Cough
Cold/Congestion

Dextromethorphan HBr
Guaifenesin

Phenylephrine HCl

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Dextromethorphan HBr

18 mg

Guaifenesin

200 mg

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Cough Suppressant • Expectorant • Nasal Decongestant

Raspberry Flavor

Alcohol Free / Sugar Free

Gluten Free / Dye Free

8 fl. oz. (240 mL)

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Tamper evident by foil seal under cap. Do not use if foil seal is broken or missing.
Manufactured for: Westminster Pharmaceuticals, LLC
Nashville, TN 37217
Rev: 04/23



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Drug Facts (continued)

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- heart disease ■ high blood pressure ■ thyroid disease ■ diabetes
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Manufactured for:
Westminster Pharmaceuticals, LLC
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dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69367-184
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	18 mg in 15 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 15 mL

PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 15 mL
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Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	RASPBERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69367-184-08	240 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/15/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH DRUG	M012	03/15/2018	

Labeler - Westminster Pharmaceuticals, LLC (079516651)

Revised: 3/2018

Westminster Pharmaceuticals, LLC