ED BRON GP- guaifenesin and phenylephrine liquid EDWARDS PHARMACEUTICALS, INC.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

ED BRON GP

Drug Facts

Active Ingredients (in each 5 mL teaspoonful)	Purpose	
Guaifenesin 100 mg	Expectorant	
Phenylephrine HCl 5 mg	Nasal Decongestant	

Uses

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

- runny nose
- sneezing
- itching of the nose or throat
- itchy, watery eyes
- nasal congestion
- reduces swelling of nasal passages
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive

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.

Do not take this product, unless directed by a doctor, if you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- difficulty in urination due to enlargement of the prostate gland

Do not take this product for persistent or chronic cough as occurs with smoking, asthma, chronic bronchitis, or emphysema, or where cough is accompanied by excessive phleam (mucus) unless directed by a doctor.

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers.

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.
- new symptoms occur

If pregnant or breastfeeding, ask a health professional before use.

Keep out of reach of children.

In case of accidental overdose, seek professional help or contact a Poison Control Center immediately.

Directions

Do not exceed recommended dosage.

Adults and children 12 years of age and over:	2 teaspoonfuls (10 mL) every 4 hours, not to exceed 12 teaspoonfuls in 24 hours, or as directed by a doctor.
Children 6 to under 12 years of age:	1 teaspoonful (5 mL) every 4 hours, not to exceed 6 teaspoonfuls in 24 hours, or as directed by a doctor.
Children under 6 years of age:	Consult a doctor.

Other information

Store at 59° - 86° F (15° - 30° C) [see USP for Controlled Room Temperature].

Inactive ingredients

Citric Acid, Methyl Paraben, Orange Flavor, Potassium Citrate, Potassium Sorbate, Propyl Paraben, Propylene Glycol, Purified Water, Sorbitol Solution 70%, and Sucralose.

Question? Comments?

PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label ED Bron GP Liquid

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NDC 0485-0208-16

ED Bron GP Liquid

Expectorant • Nasal Decongestant

Sugar Free • Alcohol Free • Dye Free

Each teaspoonful (5 mL) for oral administration contains: Guaifenesin 100 mg Phenylephrine HCl 5 mg

Orange Flavor

Tamper evident by foil seal under cap. Do not use if foil seal is broken or missing.

Manufactured for: EDWARDS Pharmaceuticals, Inc. Ripley, MS 38663

16oz. (473 mL)



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Nasal Decongestant

Uses temporarily relieves these symptoms due to the common cold, hay fever (allergic rhinitis) or other respiratory allergies: ■ runny nose ■ sneezing ■ itching of the nose of throat ■ itchy, watery eyes ■ nasal congestion ■ reduces swelling of nasal passages ■ helps loosen phlegm

(mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive

Warnings
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Drug Facts (continued)

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Question? Comments? Call 1-800-543-9560

Rev. 01/13



ED BRON GP

Liquid

GP

Bron

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guaifenesin and phenylephrine liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:0485-0208

Route of Administration ORAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength Strength 100 mg GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) **GUAIFENES IN** in 5 mL PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE -**PHENYLEPHRINE** 5 mg UNII:1WS297W6MV) **HYDROCHLORIDE** in 5 mL

Inactive Ingredients		
Ingredient Name	Strength	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)		
METHYLPARABEN (UNII: A2I8C7HI9T)		
POTASSIUM CITRATE (UNII: EE900NI6FF)		
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)		
PROPYLPARABEN (UNII: Z8IX2SC1OH)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		

SORBITOL (UNII: 506T60A25R)
SUCRALOSE (UNII: 96K6UQ3ZD4)

Product Characteristics			
Color	orange	Score	
Shape		Size	
Flavor	ORANGE	Imprint Code	
Contains			

П	Pā	ackaging			
7	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
			473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2012	

Marketing Information			
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
	06/01/2012		
	Application Number or Monograph	Application Number or Monograph Marketing Start Citation Date	

Labeler - EDWARDS PHARMACEUTICALS, INC. (195118880)

Revised: 1/2024 EDWARDS PHARMACEUTICALS, INC.