BRONCOCHEM EXPECTORANT II- acetaminophen-chlorpheniramine maleatedextromethorphan hbr-guaifenesin-phenylephrine hcl syrup LABORATORIO MAGNACHEM INTERNATIONAL SRL

BRONCOCHEM EXPECTORANT II

Warnings

Unless directed by a physician do not take this product if persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, emphysema, or if cough is accompanied by excessive phlem (mucus). Likewise if you have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate gland, if nervousness, dizziness, or sleeplesness occur, discontinue use or consult a doctor, if symptoms do not improve within 7 days or are accompained by fever, consult a doctor. A persistent cough may be a sing of a serious condition. Stop use and ask a doctor if symptoms persist or last long that 5 days (children) or 7 days (adults), tend to return, arash, or persistent headache. As with any drug, if you are pregnant or nursing a baby; seek the advice of a healh professional before using this product. Unless directed by a doctor, do not take this product if you are presently taking another product containing Pseudoephedrine HCl, or if you are taking sedatives or trankilizers; it may increase the drowsiness effect. Avoid alcoholic beverages while taking this product. Use caution when driving a motor vehicle or operating machinery.

Active Ingredients

Acetaminophen

Dextromethorphan HBr

Guaifenesin

Phenylephrine HCl

Purpose

Analgesic

Antihistaminic

Antotussive

Expectorant

Decongestant

Keep Out Of the Reach Of children

In case of accidental overdose, seek professional assistancve or contact a poison control center inmediately

Indications & Use

Bronchial congestion

Irritation of the respiratory passages

Nasal congestion

Helps loosen phlegm (mucus) and dilute bronchial secretions to make coughs more productive

Antitussive

Temporarilly relieves allergy symptoms including runny nose, sneezing, stuffy nose, itchy nose, itchy throat, irritated and watery eyes, allergic rhinitis

Dosage and Administration

Do not exceed 6 doses in a 24 hour period

Adults and chuildren 12 years and over: (10mL or cc) using metered dosage spoon every 4 hours.

Children 6 years up to 12 years: (5mL or cc) using metered dosage spoon every 4 hours

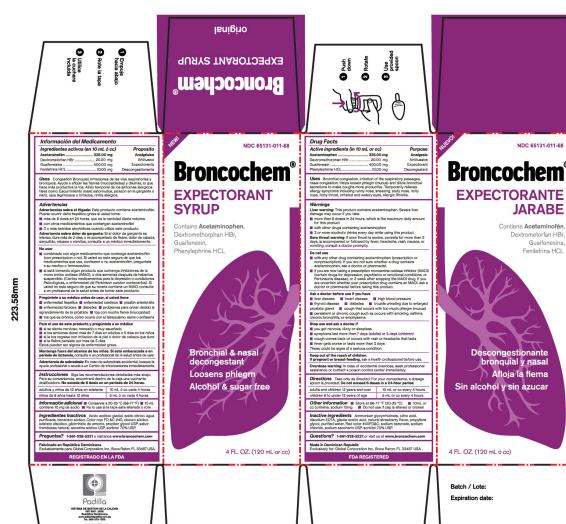
Drug Interaction Precautions

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 2 weeks after stopping the MAOI drug. If you are uncertain whether your presciption drug contains an MAOI, consult a health professional before taking this product

lactive Ingredient

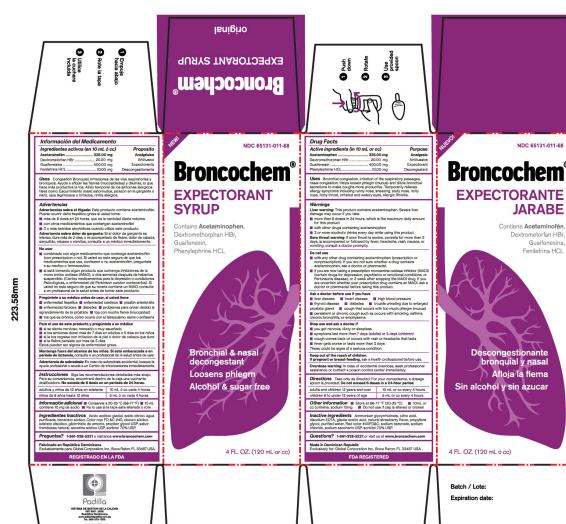
Aloe Vera, Ammonium Glycyrrhizinate, Citric acid, Disodium EDTA, Glacial Acetic Acid, Natural Raspberry flavor, Propylene Glycol USP, Purified Water, FD&C Red No.40, Sodium Benzoate, Sodium Saccharin USP, Sorbitol 70%.

Package Label Principal Display Panel



Please Favor reciclar

Guaifenesina, Fenilefrina HCL



Please Favor reciclar

Guaifenesina, Fenilefrina HCL



Ask a doctor before use if you have

- liver disease heart disease
- high blood pressure thyroid disease diabetes trouble urinating due to enlarged prostate gland cough that occurs with too much phlegm (mucus) persis cough such as occurs with smokir chronic bronchitis, or emphysema persistent or chronic

Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- symptoms last more than 7 days (adults) or 5 days (children)
- cough comes back or occurs with rash or headache that lasts
- fever gets worse or lasts more than 3 days 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.

Other information Store at 66-77 °F (20-25 °C) Do not use if cap is altered or broken

Inactive ingredients Ammonium glycyrrhizinate, citric acid, disodium EDTA, glacial acetic acid, natural strawberry flavor, propylene glycol, purified water, Red color #40FD&C, sodium benzoate, sodium

Broncochem

EXPECTORANT SYRUP

Bronchial & Nasal Decongestant Loosens Phlegm Alcohol & Sugar Free

4 FL. OZ. (120 mL or cc)

Made in Dominican Republic Exclusively for: Global Corpora Boca Raton, FL 33487 U.S.A. FDA REGISTERED

NDC 65131-011-68

Lote / Batch: Expiration date: Active Ingredients (in 10 mL or cc) Acetaminophen 325.00 mg

Dextromethorphan HBr 20.00 mg 400.00 mg Phenylephrine HCL

Analgesic Antitussive Expectoran 10.00 mg Decongestant

Uses Bronchial congestion, irritation of the respiratory passages, nasal congestion. Helps loosen phiegm (mucus) and dilute bronchial secretions to make coughs more productive.
Temporarily relieves allergy symptoms including runny nose, sneezing, stufy nose, itchy nose, itchy throat, irritated and watery eyes, allergic Rhinitis.

Directions Take only as directed. For your convenience, a dosage spoon is provided. Do not exceed 6 doses in a 24-hour period.

adults and children 12

10 mL or oc every 4 hours

children 6 to under 12

5 mL or cc every 4 hours

Purpose

Antitussive

Expectorant

See carton for complete information for use.

Questions? Please call for medical direction eekdays 9 AM to 5 PM EST. at 1-561-338-5221 or visit us at www.broncochem.com

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- liver disease heart disease ■ high blood pressure ■ thyroid disease
- diabetes trouble urinating due to enlarged prostate gland cough that occurs with too much phlegm (mucus) persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema

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Bronchial & Nasal Decongestant Loosens Phlegm Alcohol & Sugar Free

4 FL, OZ, (120 mL or cc)

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BRONCOCHEM EXPECTORANT II

acetaminophen-chlorpheniramine maleate-dextromethorphan hbr-quaifenesin-phenylephrine hcl syrup

Product Information

HUMAN OTC DRUG Item Code (Source) NDC:65131-011 **Product Type**

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

ACETAMINODUEN (LINII) 26200ITLOD (ACETAMINODUEN LINII) 26200ITLOD ACETAMINODUEN

325 ma

ACETAMINOPHEN (UNII: 3020311130) (ACETAMINOPHEN - UNII:3020311130)	ACE I AMINOPHEN	in 10 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 10 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 10 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	10 mg in 10 mL

Inactive Ingredients			
Ingredient Name	Strength		
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	40 mg in 10 mL		
SODIUM BENZOATE (UNII: OJ245FE5EU)	20 mg in 10 mL		
SODIUM CHLORIDE (UNII: 451W47IQ8X)	12 mg in 10 mL		
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	6 mg in 10 mL		
DISODIUM HEDTA (UNII: KME849MC7A)	5 mg in 10 mL		
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	2 mg in 10 mL		
SORBITOL (UNII: 506T60A25R)	2.3 mL in 10 mL		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	2 mL in 10 mL		
ACETIC ACID (UNII: Q40Q9N063P)	0.016 mL in 10 mL		
RASPBERRY (UNII: 4N14V5R27W)	0.006 mL in 10 mL		
FD&C RED NO. 40 (UNII: WZB9127XOA)	0.29 mg in 10 mL		
WATER (UNII: 059QF0KO0R)	10 mL in 10 mL		

F	Packaging					
#	t Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:65131- 011-68	1 in 1 BOX	04/21/2025			
1	-	120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product				

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M	04/21/2025	

Labeler - LABORATORIO MAGNACHEM INTERNATIONAL SRL (871446100)

Registrant - LABORATORIO MAGNACHEM INTERNATIONAL SRL (871446100)

Establishment				
Name	Address	ID/FEI	Business Operations	
LABORATORIO MAGNACHEM INTERNATIONAL SRL		871446100	manufacture(65131-011)	