

BRONCOCHEM EXPECTORANT II- acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide, guaifenesin and phenylephrine hydrochloride syrup
LABORATORIO MAGNACHEM INTERNATIONAL SRL

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.

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 phlegm (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 sleeplessness occur, discontinue use or consult a doctor, if symptoms do not improve within 7 days or are accompanied by fever, consult a doctor. A persistent cough may be a sign of a serious condition. Stop use and ask a doctor if symptoms persist or last longer than 5 days (children) or 7 days (adults), tend to return, worsen, or persistent headache. As with any drug, if you are pregnant or nursing a baby, seek the advice of a health 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 tranquilizers; 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
Chlorpheniramine Maleate
Dextromethorphan HBr
Guaifenesin
Phenylephrine HCl

Purpose

Analgesic
Antihistaminic
Antitussive
Expectorant
Decongestant

Keep Out Of the Reach Of children

In case of accidental overdose, seek professional assistance or contact a poison control center immediately

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
Temporarily 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 4 doses in a 24 hour period
Adults and children 12 years and over: (10mL or cc) using metered dosage spoon every 6 hours.
Children 6 years up to 12 years: (5mL or cc) using metered dosage spoon every 6 hours

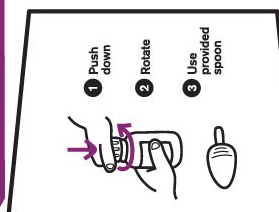
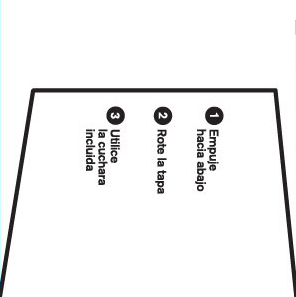
Drug Interaction Precautions

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 prescription drug contains an MAOI, consult a health professional before taking this product

Inactive 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



Información del Medicamento

Ingredientes activos (en 10 mL ó cc)	Propósito
Acetaminofén 250.00 mg	Analgésico
Clorfeniramina Maleato 4.00 mg	Antihistamínico
Dextrometorfan HBr 13.33 mg	Antitusivo
Guafenesina 200.00 mg	Expectorante
Fenilefrina HCl 5.00 mg	Descongestionante

Usos: Congestión Bronquial, Irritaciones de las vías respiratorias y broncos. Ayuda a aliviar las flemas (mucosidad) y diluirlas, lo que hace más productiva la tos. Alivio temporal de los síntomas alérgicos tales como: Escarminamiento nasal, estornudos, picazón en la garganta o nariz, ojos lagrimosos o irritados, rinitis alérgica.

Advertencias
Advertencias sobre el Hígado: Este producto contiene acetaminofén. Puede ocurrir daño hepático grave si usted toma:
 ■ más de 4 dosis en 24 horas, que es la cantidad diaria máxima
 ■ con otros medicamentos que contengan acetaminofén
 ■ 3 o más bebidas alcohólicas cuando utilice este producto
Advertencia sobre dolor de garganta: Si el dolor de garganta es intenso, dura más de 2 días, o va acompañado de fiebre, dolor de cabeza, serpillido, náusea o vómitos, consulte a un médico inmediatamente.

No usar
 ■ combinado con algún medicamento que contenga acetaminofén (con prescripción o no). Si usted no está seguro de que los medicamentos que usa, contienen o no acetaminofén, pregúntele a su médico o farmacéutico.
 ■ si está tomando algún producto que contenga inhibidores de la mono amina oxidasa (MAOI), o dos semanas después de haberlos suspendido. (Ciertos medicamentos para la depresión o condiciones Psicológicas, o enfermedad de Parkinson pueden contenerlos). Si usted no está seguro de que su receta contiene un MAOI, consulte a un profesional de la salud antes de tomar este producto.

Pregúntele a su médico antes de usar, si usted tiene
 ■ enfermedad hepática ■ enfermedad cardíaca ■ presión arterial alta ■ enfermedad tiroidea ■ diabetes ■ problemas para orinar debido al agrandamiento de la próstata ■ tos con mucha flema (mucosidad) ■ tos que es crónica, como ocurre con el tabaquismo, asma o enfisema

Para el uso de este producto y pregúntele a un médico
 ■ si se siente nervioso, mareado o muy asustado
 ■ si los síntomas duran más de 7 días en adultos o 5 días en los niños
 ■ si la tos regresa con irritación de la piel o dolor de cabeza que dure al la fiebre persiste por más de 3 días
 Estos pueden ser signos de enfermedad grave.

Mantenga fuera del alcance de los niños. Si está embarazada o en período de lactancia, consulte a un profesional de la salud antes de usar.

Advertencia de sobredosis: En caso de sobredosis accidental, busque la ayuda profesional o acuda a un Centro de Intoxicaciones inmediatamente.

Instrucciones Siga las recomendaciones detalladas más abajo. Para su conveniencia, encontrará dentro de la caja una cucharita dosificadora. No exceda de 4 dosis en un período de 24 horas.
 niños de 6 años hasta 12 años 5 mL ó cc cada 6 horas
 niños y niños de 12 años en adelante 10 mL ó cc cada 6 horas
 adultos y niños de 12 años en adelante 10 mL ó cc cada 6 horas

Información adicional ■ Conservar a 20-25 °C (68-77 °F) ■ 10 mL contiene 10 mg de sodio ■ No lo use si la tapa está alterada o rota

Ingredientes Inactivos Ácido acético glacial, ácido cítrico, agua purificada, benzoato sódico, Color rojo FD & C #40, cloruro sódico, edulcorante, glicirinato de amonio, propileno glycol USP, sabor fresa natural, sacarina sódica USP, sorbitol 70% USP.

Preguntas? 1-561-338-5221 o visítanos www.broncochem.com

Fabricado en República Dominicana
 Exclusivamente para: Global Corporation, Inc., Boca Raton, FL 33487 USA.

REGISTRADO EN LA FDA

Broncochem
 EXPECTORANT SYRUP

Contains Acetaminophen, Chlorpheniramine Maleate, Dextromethorphan HBr, Guaifenesin, Phenylephrine HCl

Bronchial & nasal decongestant
 Loosens phlegm
 Alcohol & sugar free

4 FL. OZ. (120 mL or cc)

Drug Facts

Active ingredients (in 10 mL or cc)	Purpose
Acetaminophen 250.00 mg	Analgasic
Chlorpheniramine Maleate 4.00 mg	Antihistamine
Dextromethorphan HBr 13.33 mg	Antitussive
Guaifenesin 200.00 mg	Expectorant
Phenylephrine HCl 5.00 mg	Decongestant

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

Warnings
Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:
 ■ more than 4 doses in 24 hrs, which is the maximum daily amount for this product
 ■ with other drugs containing acetaminophen
 ■ 3 or more alcoholic drinks every day while using this product
Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use
 ■ with any other drug containing acetaminophen (prescription or nonprescription), if you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
 ■ 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 week after stopping the MAOI drug. If you are uncertain whether your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

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)
 ■ persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema

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.

Keep out of the reach of children.
 If pregnant or breast-feeding, ask a health professional before use.

Overdose warning: In case of accidental overdose, seek professional assistance or contact a poison control center immediately.

Directions: Take only as directed. For your convenience, a dosage spoon is provided. **Do not exceed 4 doses in a 24 hour period.**
 adults and children 12 years and over 10 mL or cc every 6 hour
 children 6 to under 12 years 5 mL or cc every 6 hour

Other information ■ Store at 68-77 °F (20-25 °C) ■ 10mL or cc contains sodium 10mg ■ Do not use if cap is altered or broken

Inactive ingredients Ammonium glycyrrhizate, citric acid, disodium EDTA, glacial acetic acid, natural raspberry flavor, propylene glycol, purified water, Red color #40FD&C, sodium benzoate, sodium chloride, sodium saccharin USP, sorbitol 70% USP.

Questions? 1-561-338-5221 or visit us at www.broncochem.com

Made in Dominican Republic
 Exclusively for: Global Corporation Inc., Boca Raton, FL 33487 USA.

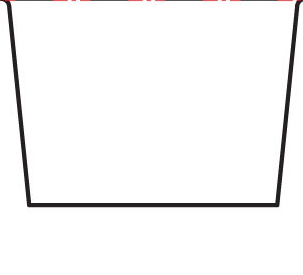
FDA REGISTERED

Broncochen
 EXPECTORANTI JARABI

Contiene Acetaminofén, Clorfeniramina Maleato, Dextrometorfan HBr, Guafenesina, Fenilefrina HCl

Descongestionante bronquial y nasal
 Alivia la flema
 Sin alcohol y sin azúcar

4 FL. OZ. (120 mL ó cc)



Padilla
 SISTEMA DE GESTIÓN DE LA CALIDAD
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PRESERVADO DE BARNIZ Y TINTA

PRESERVADO DE BARNIZ Y TINTA

Batch / Lote: PRESERVADO DE BARNIZ Y TINTA
Expiration date: PRESERVADO DE BARNIZ Y TINTA

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

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:65131-116
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (ACETAMINOPHEN)	ACETAMINOPHEN	250 mg in 10 mL
CHLORPHENIRAMINE MALEATE (CHLORPHENIRAMINE)	CHLORPHENIRAMINE MALEATE	4 mg in 10 mL
DEXTROMETHORPHAN HYDROBROMIDE (DEXTROMETHORPHAN)	DEXTROMETHORPHAN HYDROBROMIDE	13.33 mg in 10 mL
GUAIFENESIN (GUAIFENESIN)	GUAIFENESIN	200 mg in 10 mL
PHENYLEPHRINE HYDROCHLORIDE (PHENYLEPHRINE)	PHENYLEPHRINE	5 mg in 10 mL

Inactive Ingredients		Strength
Ingredient Name		
SACCHARIN SODIUM		40 mg in 10 mL
SODIUM BENZOATE		20 mg in 10 mL
SODIUM CHLORIDE		12 mg in 10 mL
AMMONIUM GLUCYRRHIZATE		6 mg in 10 mL
DISODIUM HEDTA		5 mg in 10 mL
CITRIC ACID MONOHYDRATE		2 mg in 10 mL
SORBITOL		2.3 mL in 10 mL
PROPYLENE GLYCOL		2 mL in 10 mL
ACETIC ACID		0.016 mL in 10 mL
RASPBERRY		0.006 mL in 10 mL
FD&C RED NO. 40		0.29 mg in 10 mL
WATER		10 mL in 10 mL

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65131-116-87	1 in 1 BOX	12/30/2016	
1		120 mL in 1 BOTTLE, PLASTIC; Combination Product Type = C112160		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	12/30/2016	

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(65131-116)

Revised: 12/2016

LABORATORIO MAGNACHEM INTERNATIONAL SRL