

BRONCOCHEM MAXIMUM COUGH- dextromethorphan hbr-guaifenesin syrup

LABORATORIO MAGNACHEM INTERNATIONAL SRL

BRONCOCHEM MAXIMUM COUGH

Warning Secction

Do not take this product for persitent or chronic cough such as occurs with smoking, asthma, or emphysema or if cough is accompainied with excessive phlegm (mucus) unless directed by a doctor. Persistent cough may be the sign of a serious condition. Stop use and dask a doctor if symptoms persist or last more than 5 days (children) or 7 days (adults), tends to recur, is accompainied or followed by fever, headache, rash, swelling, nausea or vomiting, consult a doctor. Do not take this product if you are hypersensitive to any of the ingredients. As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product. Avoid alcoholic beverages while taking this product.

Active Ingredients

Guaifenesin

Dextromethorphan HBr

Purpose

Expectorant

Antitussive

Keep out of the reach of children

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

Indications and Usage

Temporarily relieves cough due to minor throat and bronchial irritation occuring with common cold.

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

This new formulation with aloe results a natural cleanser, penetrates tissue, bactericidal, viruscidal, and fungicidal, enhances normal cell proliferation and moisturizes tissues (this statements are not yet evaluated by the Food and Drugs Administration "FDA")

Broncochem Maximum Cough has not drowsiness effect.

Work in chest congestion, its specially formulated for children and adults.

Dossage and Administration

Do not exceed 6 doses in a 24 hour period

Adults and children 12 years and over: (10mL or cc) every 4 hours

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

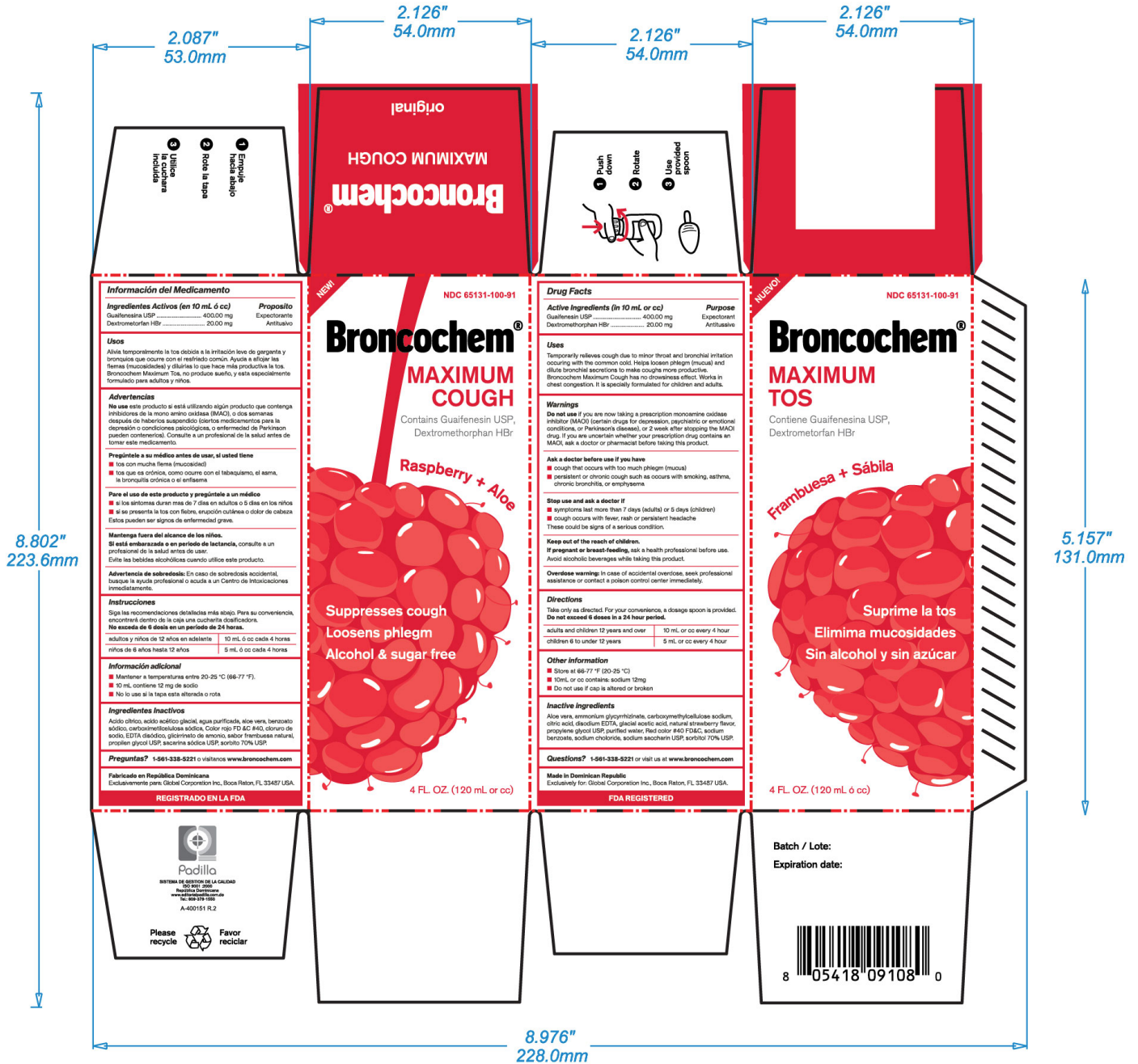
Drug Interactions Section

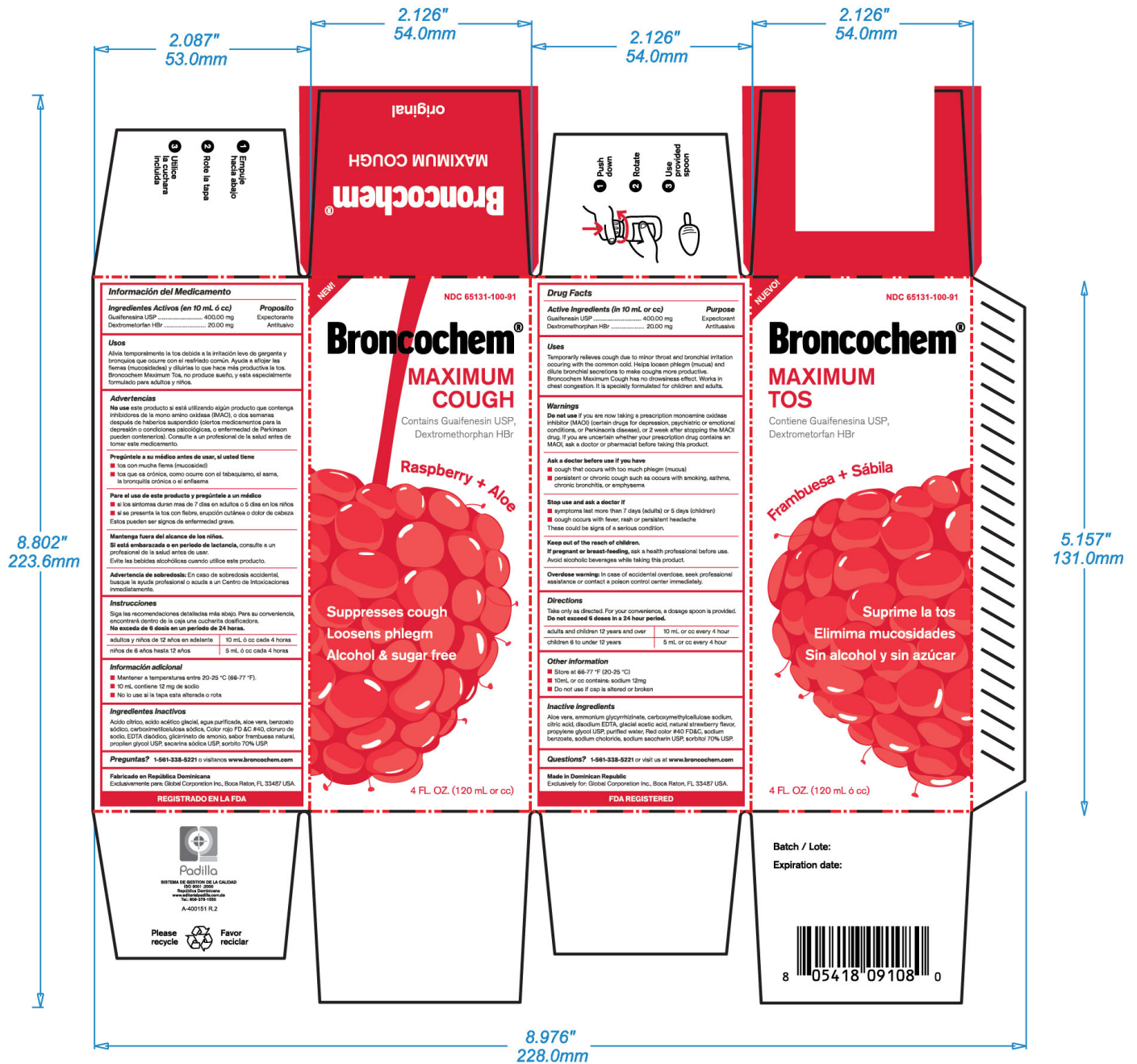
Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI), (certain drugs for depression, psychiatric or emotional conditions or Parkinsons disease), or 2 weeks after stopping the MAOI drug. Id you are uncertain ehether your prescription drug contains an MAOI, consult a health professional before taking this product

Inactive Ingredient Section

Aloe Vera, Ammonium Glycyrrhizinate, Citric Acid, Disodium HEDTA, Glacial Acetic Acid, Strawberry flavor, Propylene Glycol, Purified Water, FD&C Red 40, Sodium Benzoate, Sodium Chloride, Sodium Saccharin, Sorbitol, Carboxymethylcellulose sodium, Total Sodium content: 12mg (in 10mL or cc)

Package Label Principal Display Panel





Package Label Principal Display Panel

Warnings

Ask a doctor before use if you have

■ 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

■ symptoms last more than 7 days (adults) or 5 days (children)

■ cough occurs with fever, rash or persistent headache

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.

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

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

Inactive ingredients Aloe vera, ammonium glycyrrhizinate, carboxymethylcellulose sodium, citric acid, disodium EDTA, glacial acetic acid, natural strawberry flavor, propylene glycol USP, purified water, Red color #40 FD&C, sodium benzoate, sodium chlorate, sodium saccharin USP, sorbitol 70% USP.

Broncochem[®]

MAXIMUM COUGH

Suppresses Cough

Loosens Phlegm

Alcohol & Sugar Free

4 FL. OZ. (120 mL or cc)

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

FDA REGISTERED

Lote / Batch:
Expiration date:

Active Ingredients (in 10 mL or cc)

Guaifenesin USP 400.00 mg Expectorant
Dextromethorphan HBr 20.00 mg Antitussive

Purpose

Uses

Temporarily relieves cough due to minor throat and bronchial irritation occurring with the common cold. Helps loosen phlegm (mucus) and dilute bronchial secretions to make coughs more productive. Broncochem Maximum Cough has no drowsiness effect. Works in chest congestion. It is specially formulated for children and adults.

Directions

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

adults and children 12 years and over

10 mL or cc every 4 hour

children 6 to under 12 years

5 mL or cc every 4 hour

See carton for complete information for use.

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

BRONCOCHEM MAXIMUM COUGH

dextromethorphan hbr-guaifenesin syrup

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65131-100
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
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
Inactive Ingredients			
Ingredient Name			Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)			4 mg in 10 mL
SODIUM BENZOATE (UNII: OJ245FE5EU)			20 mg in 10 mL
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)			6.8 mg in 10 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)			12 mg in 10 mL
FD&C RED NO. 40 (UNII: WZB9127XOA)			0.508 mg in 10 mL
DISODIUM HEDTA (UNII: KME849MC7A)			5 mg in 10 mL
AMMONIUM GLCYRRHIZATE (UNII: 3VRD35U26C)			20 mg in 10 mL
SACCHARIN SODIUM (UNII: SB8ZUX40TY)			30 mg in 10 mL
ACETIC ACID (UNII: Q40Q9N063P)			0.016 mL in 10 mL
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			1.6 mL in 10 mL
RASPBERRY (UNII: 4N14V5R27W)			0.04 mL in 10 mL
SORBITOL (UNII: 506T60A25R)			2 mL in 10 mL

ALOE VERA LEAF (UNII: ZY81Z83H0X)	20 mg in 10 mL
WATER (UNII: 059QF0KO0R)	10 mL in 10 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65131-100-91	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(65131-100)