BRONCOCHEM MAXIMUM COUGH- dextromethorphan hydrobromide and guaifenesin 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 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 accompained 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

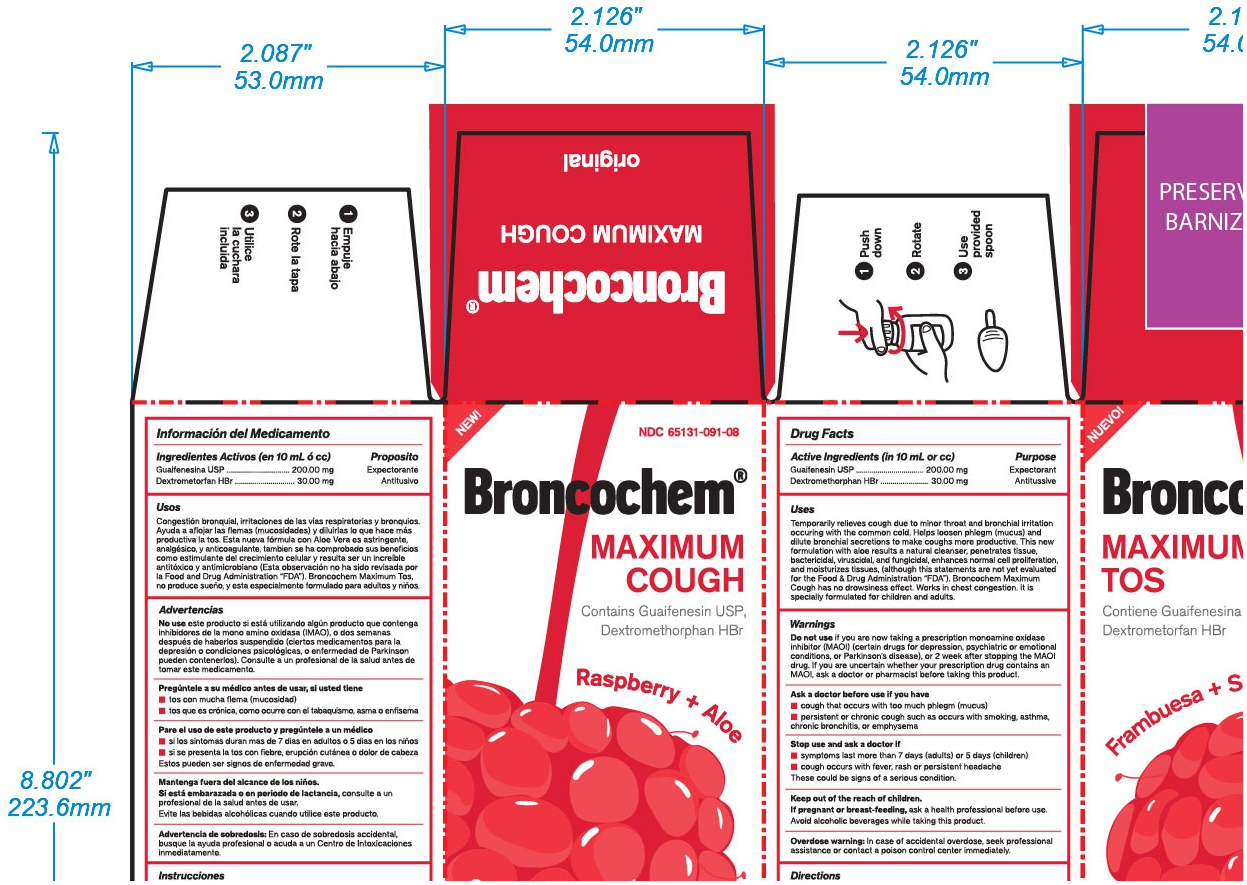
Drug Interactions Section

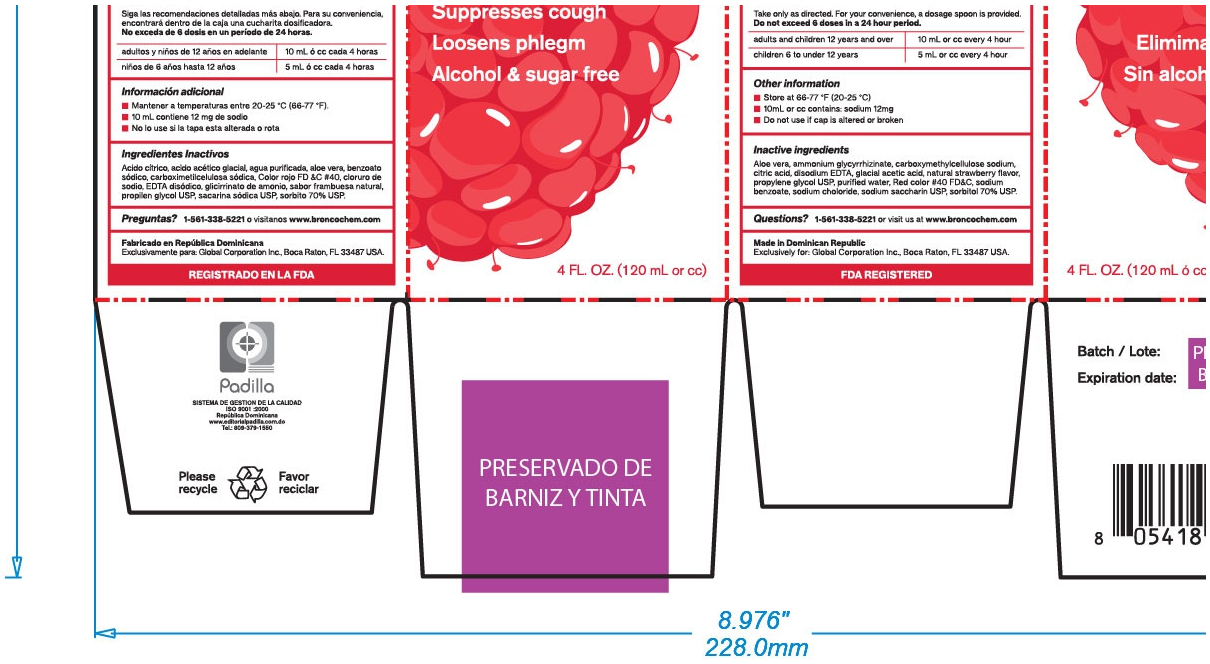
Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI), (certain drugs for depression, psychiatric or emotional conditions or Parkinsons disease), or 2 weeks after stopping the MAOI drug. Id you are uncertain ehether your prescription drug contains an MAOI, consult a health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





BRONCOCHEM MAXIMUM COUGH

dextromethorphan hbr-gyaifenesin syrup

Product Information			
Product Type	HUMAN OTC DRUG LABEL	**Item Code (Source)**	NDC:65131-091
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (DEXTROMETHORPHAN)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 10 mL
GUAIFENESIN (GUAIFENESIN)	GUAIFENESIN	200 mg in 10 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID	4 mg in 10 mL
SODIUM BENZOATE	20 mg in 10 mL
CARBOXYMETHYLCELLULOSE SODIUM	6.8 mg in 10 mL
SODIUM CHLORIDE	12 mg in 10 mL
FD&C RED NO. 40	0.508 mg in 10 mL
DISODIUM EDTA	5 mg in 10 mL
AMMONIUM GLYCYRRHIZATE	20 mg in 10 mL
SACCHARIN SODIUM	30 mg in 10 mL
ACETIC ACID	0.016 mL in 10 mL
PROPYLENE GLYCOL	1.6 mL in 10 mL
RASPBERRY	0.04 mL in 10 mL
SORBITOL	2 mL in 10 mL
ALOE VERA LEAF	20 mg in 10 mL
WATER	10 mL in 10 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65131-091-08	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 final	part341	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(65131-091)