

**BRONCOCHEM MAXIMUM COUGH KIDS- dextromethorphan hbr-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.*

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**BRONCOCHEM MAXIMUM COUGH KIDS**

**Warnings**

Do not Use

If you are now taking a prescription monoamine oxidase inhibitor (MAOI) or two weeks after stopping the MAOI drug (certain drugs for depression, psychiatric or emotional conditions may contain MAOI), if you are uncertain whether your prescription contains MAOI ask a doctor or pharmacist before taking this product.

**Uses**

Temporarily relieves cough due to minor throat and Bronchial irritation occurring with common cold. Helps loosen phlegm (mucus) and dilute bronchial secretions to make cough more productive.

**Active Ingredients**

Guaifenesin.....100.00mg

Dextromethorphan HBr.....10.00mg

**Ask a doctor before use if your kid have**

Cough that occurs with too much phlegm (mucus)

Persistent or chronic cough, asthma or emphysema

If your kid is allergic to any other component of this formula

**Stop use and ask a doctor if**

Symptoms last more than 5 days

Cough occurs with fever, rash or persistent headache, this could be signs of a serious condition

**keep out of the reach of children**

Keep out of the reach of children

**Overdose Warnigs**

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

Children from 6 to 12 years-----15mL or cc every 6 hours

Children from 2 to 6 years-----7.5mL or ccevery 6 hours

Children under 2 years, ask your doctor

### **Other Information**

Store al 66-77

### **Inactive Ingredients**

Propylene glycol, Glycerin, Sorbitol 70%, Povidone, Sodium Citrate Dihydrate, Sodium Chloride, Green color, White Vanilla Flavor, Aloe Vera, Methy Paraben USP, Propil Paraben USP. Peppermint Flavor, Bubble Gum Flavor, Purified Water

### **Quiestions**

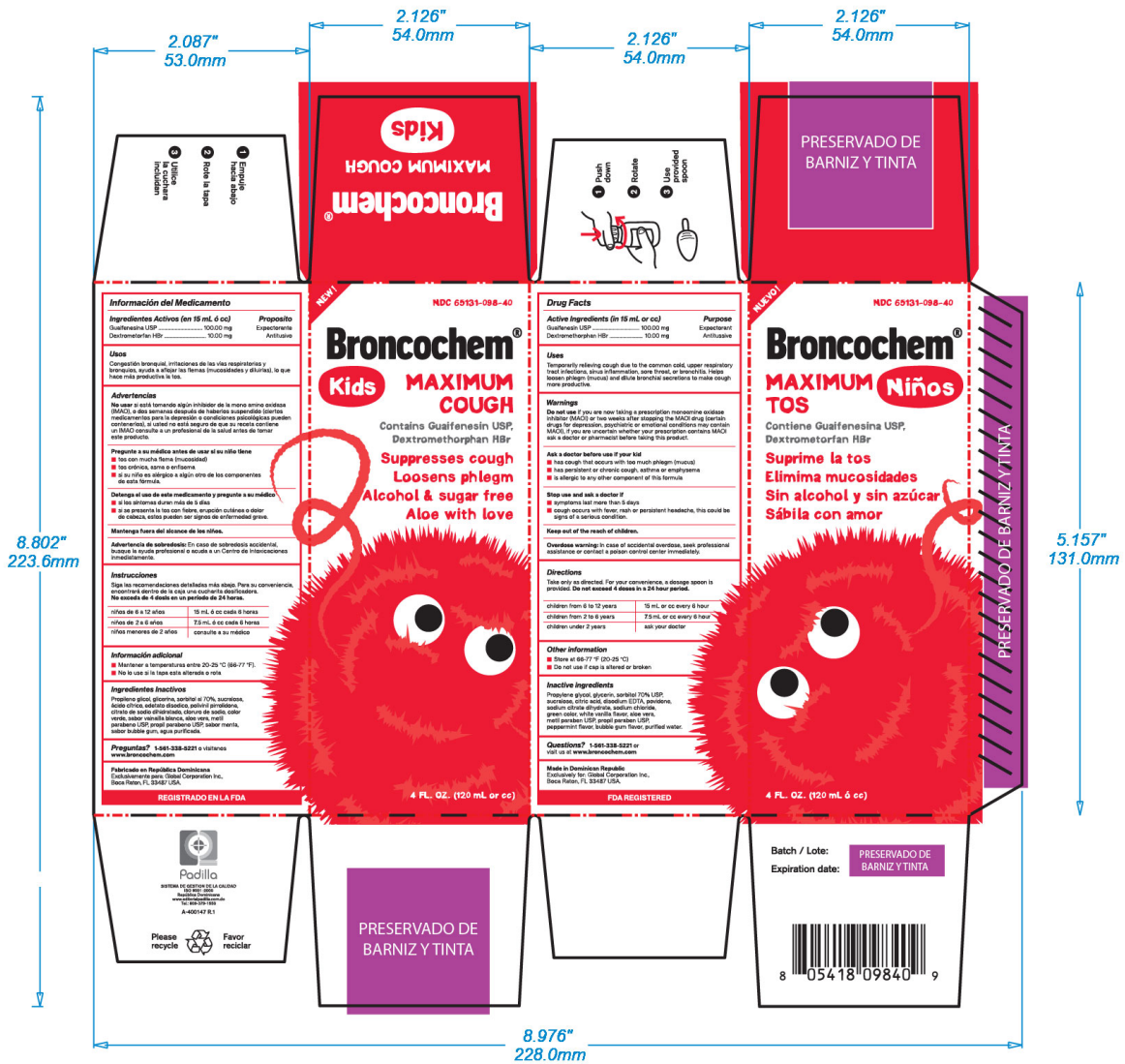
1-561-338-5221 or visit us at [www.broncochem.com](http://www.broncochem.com)

### **Purpose**

Guaifenesin.....Expectorant

Dextromethorphan HBr.....Antotussive

### **Package Label Principal Display Panel**



Package Label Principal Display Panel

<p><b>Warnings</b></p> <p>Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) or two weeks after stopping the MAOI drug (certain drugs for depression, psychiatric or emotional conditions may contain MAOI). If you are uncertain whether your prescription contains MAOI ask a doctor or pharmacist before taking this product.</p> <p><b>Ask a doctor before use if your kid</b></p> <ul style="list-style-type: none"> <li>has cough that occurs with too much phlegm (mucus)</li> <li>has persistent or chronic cough, asthma or emphysema</li> <li>is allergic to any other component of this formula</li> </ul> <p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>symptoms last more than 5 days</li> <li>cough occurs with fever, rash or persistent headache, this could be signs of a serious condition</li> </ul> <p><b>Keep out of the reach of children.</b></p> <p><b>Inactive Ingredients</b> Propylene glycol, glycerin, sorbitol 70% USP, sucralose, citric acid, disodium EDTA, povidone, sodium citrate dihydrate, sodium chloride, green color, white vanilla flavor, aloe vera, methyl paraben USP, propyl paraben USP, peppermint flavor, bubble gum flavor, purified water.</p>	NDC 65131-098-40		<p><b>Active Ingredients (in 15 mL or cc)</b></p> <table border="1"> <tr> <td>Guaifenesin USP</td> <td>100.00 mg</td> <td>Expectorant</td> </tr> <tr> <td>Dextromethorphan HBr</td> <td>10.00 mg</td> <td>Antitussive</td> </tr> </table>	Guaifenesin USP	100.00 mg	Expectorant	Dextromethorphan HBr	10.00 mg	Antitussive
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Dextromethorphan HBr	10.00 mg	Antitussive							
<h1>Broncochem®</h1> <h2>MAXIMUM COUGH</h2> <p><b>Suppresses cough</b> <b>Loosens phlegm</b> <b>Alcohol &amp; sugar free</b> <b>Aloe with love</b></p> <div style="float: right; border: 2px solid red; border-radius: 50%; padding: 10px; color: white; font-weight: bold; font-size: 1.2em;">Kids</div>		<p><b>Uses</b> Temporarily relieving cough due to the common cold, upper respiratory tract infections, sinus inflammation, sore throat, or bronchitis. Helps loosen phlegm (mucus) and dilute bronchial secretions to make cough more productive.</p> <p><b>Directions</b> Take only as directed. For your convenience, a dosage spoon is provided. <b>Do not exceed 4 doses in a 24 hour period.</b></p> <table border="1"> <tr> <td>children from 6 to 12 years</td> <td>15 mL or cc every 6 hour</td> </tr> <tr> <td>children from 2 to 6 years</td> <td>7.5 mL or cc every 6 hour</td> </tr> <tr> <td>children under 2 years</td> <td>ask your doctor</td> </tr> </table> <p><b>Other information</b> ■ Store at 66-77 °F (20-25 °C) ■ Do not use if cap is altered or broken</p> <p>See carton for complete information for use.</p> <p><b>Questions?</b> Please call for medical direction weekdays 9 AM to 5 PM EST. at 1-561-338-5221 or visit us at <a href="http://www.broncochem.com">www.broncochem.com</a></p>	children from 6 to 12 years	15 mL or cc every 6 hour	children from 2 to 6 years	7.5 mL or cc every 6 hour	children under 2 years	ask your doctor	
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<p><b>4 FL. OZ. (120 mL or cc)</b></p> <p>Made in Dominican Republic Exclusively for: Global Corporation Inc., Boca Raton, FL 33487 U.S.A.</p>	<p><b>FDA REGISTERED</b></p> <p>Lot: / Batch: Expiration date: No Barniz</p>								

## BRONCOCHEM MAXIMUM COUGH KIDS

dextromethorphan hbr-guaifenesin syrup

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:65131-180
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 15 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 15 mL

### Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	2.25 mL in 15 mL
GLYCERIN (UNII: PDC6A3C0OX)	2.25 mL in 15 mL
SORBITOL (UNII: 506T60A25R)	2.25 mL in 15 mL
SUCRALOSE (UNII: 96K6UQ3ZD4)	15 mg in 15 mL
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	45 mg in 15 mL
DISODIUM HEDTA (UNII: KME849MC7A)	1.35 mg in 15 mL
POVIDONE K90 (UNII: RDH86HJV5Z)	270 mg in 15 mL
SODIUM CITRATE (UNII: 1Q73Q2JULR)	45 mg in 15 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	9.37 mg in 15 mL
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	0.036 mg in 15 mL
VANILLA (UNII: Q74T35078H)	0.0006 mL in 15 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	30 mg in 15 mL

<b>METHYL PARABEN</b> (UNII: A2I8C7HI9T)	15 mg in 15 mL
<b>PEPPERMINT</b> (UNII: V95R5KMY2B)	0.001 mL in 15 mL
<b>PROPYL PARABEN</b> (UNII: Z8IX2SC1OH)	2.25 mg in 15 mL
<b>WATER</b> (UNII: 059QF0K00R)	15 mL in 15 mL

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	BUBBLE GUM	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65131-180-98	1 in 1 BOX	05/01/2017	
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 final	part341	05/01/2017	

**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(65131-180)

Revised: 4/2017

LABORATORIO MAGNACHEM INTERNATIONAL SRL