

**BRONCOCHEM KIDS ALLERGY CONTROL- chlorpheniramine maleate-dextromethorphan
hbr syrup**

LABORATORIO MAGANCEHM 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 KIDS ALLERGY CONTROL

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

active ingredients

Dextromethorphan HBr.....10.00mg

Chlorpheniramine maleate...2.00mg

Uses

Temporarily relieves cold symptoms, cough, helps loosen phlegm (mucus) and dilute bronchial secretions to make coughs more productive.

Reduces allergic symptoms like runny nose and sneezing, irritated and watery eyes, Itchy nose, Itchy throat, Allergy rhinitis

Ask a doctor before use if your kid have

Cough with lots of phlegm

Chronic cough, asthma or emphysema

Respiratory problems

Chronic bronchitis

If your child is allergic to another component of this formula

Stop use and ask a doctor if

Symptoms last more than 5 days

If your child feels dizziness, nervous or cannot sleep

If the cough present fever and headache, this could be signs of a serious conditions

If new symptoms occur

Keep out of the reach of children

Keep out of the reach of children

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

Children from 6 to 12 years-----10mL or cc every 6 hours

Children from 2 to 6 years-----5mL or cc every 6 hours

Children under 2 years, ask your doctor

Other information

Store at 66-77°F (20-25°C), do not use if security cap is altered or broken

Inactive Ingredients

Propylene glycol, Glycerin, Sorbitol 70%, Sucralose, Povidone, Sodium Chloride, Aloe vera, Methylparaben USP, Propylparaben USP, Ascorbic acid, Color Yellow #5, Disodium Edta, Orange flavor, Sodium hydroxide, Purified water

Questions?

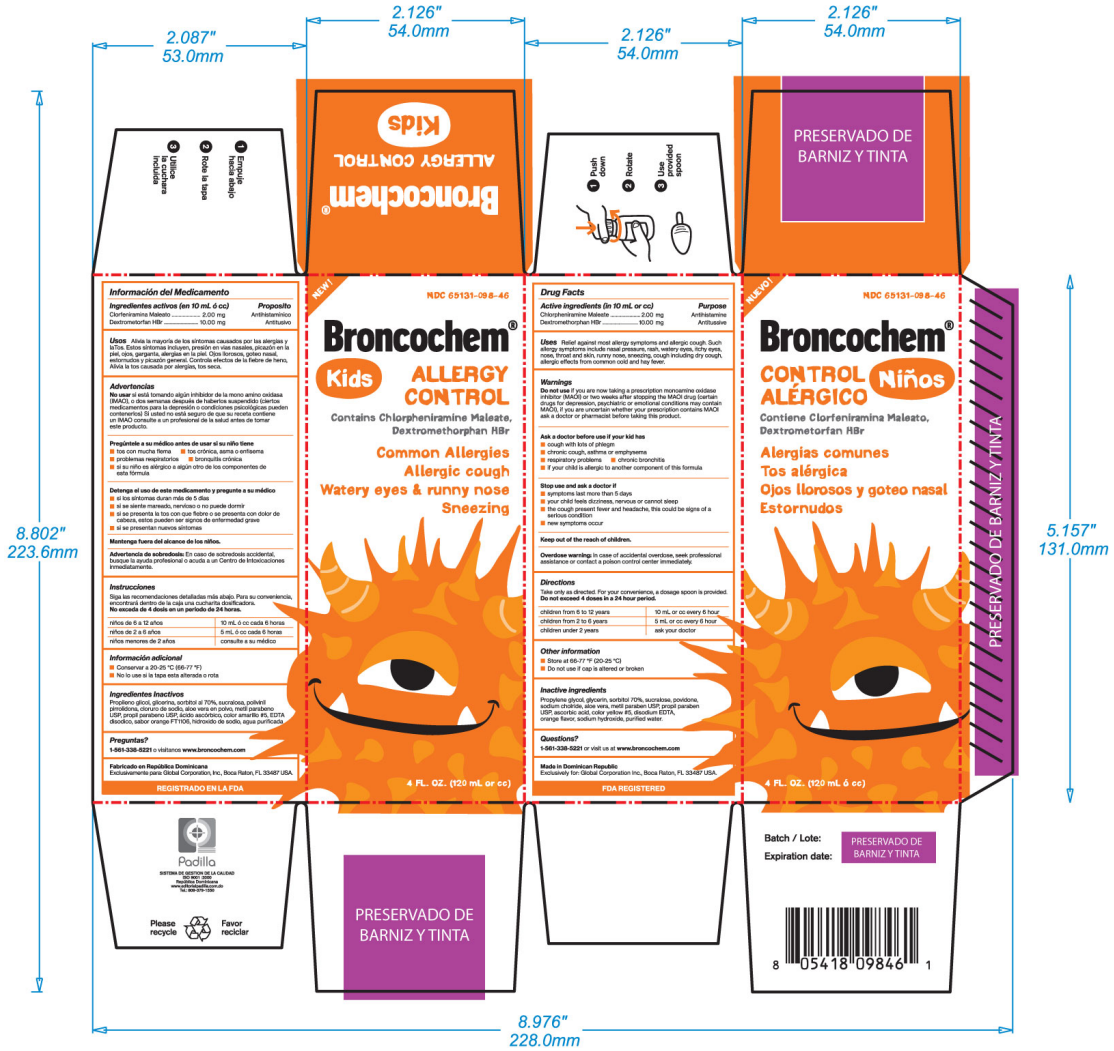
1-561-338-5221 or visit us at www.broncochem.com

Purpose

Dextromethorphan HBr-----Antitussive

Chlorpheniramine maleate--Antihistamine

Package Label Principal Display Panel



Package Label Principal display Panel

<p>Warnings</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>Ask a doctor before use if your kid has</p> <ul style="list-style-type: none"> ■ cough with lots of phlegm ■ chronic cough, asthma or emphysema ■ respiratory problems ■ chronic bronchitis ■ if your child is allergic to another component of this formula <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> ■ symptoms last more than 5 days ■ your child feels dizziness, nervous or cannot sleep ■ the cough present fever and headache, this could be signs of a serious condition ■ new symptoms occur <p>Keep out of the reach of children.</p>	NDC 65131-098-46		<p>Active Ingredients (in 10 mL or cc)</p> <table border="1"> <tr> <td>Chlorpheniramine Maleate</td> <td>2.00 mg</td> <td>Antihistamine</td> </tr> <tr> <td>Dextromethorphan HBr</td> <td>10.00 mg</td> <td>Antitussive</td> </tr> </table>	Chlorpheniramine Maleate	2.00 mg	Antihistamine	Dextromethorphan HBr	10.00 mg	Antitussive
	Chlorpheniramine Maleate	2.00 mg	Antihistamine						
Dextromethorphan HBr	10.00 mg	Antitussive							
<p style="font-size: 2em; font-weight: bold; text-align: center;">Broncochem®</p> <p style="font-weight: bold; text-align: center; background-color: orange; color: white; padding: 5px;">ALLERGY CONTROL</p> <p style="font-weight: bold; text-align: center;">Common Allergies</p> <p style="font-weight: bold; text-align: center;">Allergic cough</p> <p style="font-weight: bold; text-align: center;">Watery eyes & runny nose</p> <p style="font-weight: bold; text-align: center;">Sneezing</p> <div style="text-align: right; border: 1px solid orange; border-radius: 50%; width: 40px; height: 40px; display: flex; align-items: center; justify-content: center; margin: 10px auto;"> Kids </div>	<p>Uses Relief against most allergy symptoms and allergic cough. Such allergy symptoms include nasal pressure, rash, watery eyes, itchy eyes, nose, throat and skin, runny nose, sneezing, cough including dry cough, allergic effects from common cold and hay fever.</p> <p>Directions Take only as directed. For your convenience, a dosage spoon is provided. Do not exceed 4 doses in a 24 hour period.</p> <table border="1" style="width: 100%;"> <tr> <td>children from 6 to 12 years</td> <td>10 mL or cc every 6 hour</td> </tr> <tr> <td>children from 2 to 6 years</td> <td>5 mL or cc every 6 hour</td> </tr> <tr> <td>children under 2 years</td> <td>ask your doctor</td> </tr> </table> <p>Other information ■ Store at 66-77 °F (20-25 °C) ■ Do not use if cap is altered or broken</p>		children from 6 to 12 years	10 mL or cc every 6 hour	children from 2 to 6 years	5 mL or cc every 6 hour	children under 2 years	ask your doctor	<p>See carton for complete information for use.</p> <p>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</p>
children from 6 to 12 years	10 mL or cc every 6 hour								
children from 2 to 6 years	5 mL or cc every 6 hour								
children under 2 years	ask your doctor								
<p>Inactive ingredients Propylene glycol, glycerin, sorbitol 70%, sucralose, povidone, sodium chloride, aloe vera, metil paraben USP, propil paraben USP, ascorbic acid, color yellow #5, disodium EDTA, range flavor, sodium hydroxide, purified water.</p>	<p>4 FL. OZ. (120 mL or cc)</p> <p>Made in Dominican Republic Exclusively for: Global Corporation Inc., Boca Raton, FL 33487 U.S.A.</p>	<p>FDA REGISTERED</p> <p>Lote / Batch: Expiration date:</p>							

BRONCOCHEM KIDS ALLERGY CONTROL

chlorpheniramine maleate-dextromethorphan hbr syrup

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65131-418
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 mg in 10 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 10 mL

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	1.5 mL in 10 mL
GLYCERIN (UNII: PDC6A3C0OX)	2 mL in 10 mL
SORBITOL (UNII: 506T60A25R)	2 mL in 10 mL
SUCRALOSE (UNII: 96K6UQ3ZD4)	8.33 mg in 10 mL
POVIDONE K90 (UNII: RDH86HJV5Z)	100 mg in 10 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	6.25 mg in 10 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	4 mg in 10 mL
METHYL PARABEN (UNII: A2I8C7HI9T)	10 mg in 10 mL
PROPYL PARABEN (UNII: Z8IX2SC1OH)	1.5 mg in 10 mL
ASCORBIC ACID (UNII: PQ6CK8PD0R)	66 mg in 10 mL
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	0.5 mg in 10 mL
DISODIUM HEDTA (UNII: KME849MC7A)	0.9 mg in 10 mL

ORANGE (UNII: 5EVU04N5QU)	0.0016 mg in 10 mL
SODIUM HYDROXIDE (UNII: 55X04QC32I)	13.33 mg in 10 mL
WATER (UNII: 059QF0KO0R)	10 mL in 10 mL

Product Characteristics

Color		Score	
Shape		Size	
Flavor	ORANGE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65131-418-09	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 MAGANCEHM INTERNATIONAL SRL (871446100)

Registrant - LABORATORIO MAGNACHEM INTERNATIONAL SRL (871446100)

Establishment

Name	Address	ID/FEI	Business Operations
LABORATORIO MAGNACHEM INTERNATIONAL SRL		871446100	manufacture(65131-418)

Revised: 4/2017

LABORATORIO MAGANCEHM INTERNATIONAL SRL