

BRONCOCHEM ALLERGY CONTROL- chlorpheniramine maleate-phenylephrine hcl 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 ALLERGY CONTROL

Warnings

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

Nasal congestion, irritation of the upper respiratory passages, temporarily reduces allergy, swelling of nasal passages, sneezing, itching of the nose or throat, itchy watery eyes, allergic rhinitis.

Active ingredients (in 10 mL or cc)

Chlorpheniramine Maleate.....4.00mg (antihistamine)

Phenylephrine HCl.....5.00mg (Decongestant)

Ask a doctor or Pharmacist if you

Are taking sedatives or tranquilizers

When Using this Product

Excitability may occur, especially in children.

May cause marked drowsiness

Avoid alcoholic drinks

Alcohol, sedatives and tranquilizers may increase drowsiness

Be careful when driving or operating machinery

Stop Use and Ask a Doctor If

Nervousness, dizziness or sleeplessness occur.

Symptoms last more than five days.

If fever is presented that last more than 3 days or headache appears, this could be signs of a serious condition.

Keep Out of the Reach of children

Keep out of the reach of children.

If pregnant or breast-feeding, ask a doctor before taking this product.

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 from 12 years above 10mL or cc every 6 hours.

Children from 6 to 12 years 5mL or cc every 6 hours.

Children under 6 years, ask your doctor.

Other Information

Store at 66-77

Inactive Ingredients

Propylene glycol, Glycerin, Sorbitol 70% USP, sucralose, Povidone, Sodium chloride, Aloe Vera, Metil paraben USP, Propil paraben USP, Propyl gallate, Citric acid, Sodium citrate dihydrate, EDTA disodium, Grape flavor, Purified water.

Questions

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

Made in Dominican Republic by Laboratorio Magnachem International SRL to Global Corporation Inc.
Boca Raton, Fl 33487

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



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<p>Warnings</p> <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> ■ a breathing problem such as emphysema or chronic bronchitis ■ glaucoma ■ trouble urinating due to an enlarged prostate gland ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes mellitus <p>Ask a doctor or pharmacist if you</p> <ul style="list-style-type: none"> ■ are taking sedatives or tranquilizers <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> ■ nervousness, dizziness or sleeplessness occur ■ symptoms last more than 5 days ■ if fever is presented that last more than 3 days or headache appears, this could be signs of a serious condition <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of the reach of children.</p> <p>Overdose warning: In case of accidental overdose, seek professional assistance or contact a poison control center immediately.</p>	NDC 65131-098-47		<p>Active Ingredients (in 10 mL or cc)</p> <table border="0"> <tr> <td>Chlorpheniramine Maleate</td> <td>4.00 mg</td> <td>Antihistamine</td> </tr> <tr> <td>Phenylephrine HCl</td> <td>10.00 mg</td> <td>Decongestant</td> </tr> </table>	Chlorpheniramine Maleate	4.00 mg	Antihistamine	Phenylephrine HCl	10.00 mg	Decongestant
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<h1>Broncochem®</h1> <h2>ALLERGY CONTROL</h2> <p>Common Allergies</p> <p>Watery eyes and runny nose</p> <p>Nasal congestions</p> <p>Sneezing</p> <p>Alcohol & sugar free</p>	<p>Uses Temporarily reduces allergy symptoms, such as swelling of nose and throat, nasal passages, itchy nose, throat, or eyes, watery nose and eyes, allergic rhinitis nasal congestion and upper respiratory passages.</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"> <tr> <td>adults and children 12 years and over</td> <td>10 mL or cc every 6 hour</td> </tr> <tr> <td>children 6 to under 12 years</td> <td>5 mL or cc every 6 hour</td> </tr> <tr> <td>children under 6 years</td> <td>ask your doctor</td> </tr> </table> <p>Other information ■ Store at 86-77 °F (20-25 °C) ■ Do not use if cap is altered or broken</p>		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	children under 6 years	ask your doctor	
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<p>Inactive Ingredients Propylene glycol, glycerin, sorbitol 70% USP, sucralose, povidone, sodium chloride, aloe vera, metil paraben USP, propil paraben USP, propyl gallate, citric acid, sodium citrate dihydrate, EDTA disodium, grape flavor, 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>Lot# / Batch: Expiration date:</p>	<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>						

BRONCOCHEM ALLERGY CONTROL

chlorpheniramine maleate-phenylephrine hcl syrup

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65131-098
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	4 mg in 10 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	10 mg in 10 mL

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	1.2 mL in 10 mL
GLYCERIN (UNII: PDC6A3C0OX)	2 mL in 10 mL
SORBITOL (UNII: 506T60A25R)	2 mL in 10 mL
SUCRALOSE (UNII: 96K6UQ3ZD4)	7.5 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
PROPYL GALLATE (UNII: 8D4SNN7V92)	1 mg in 10 mL
CITRIC ACID ACETATE (UNII: DSO12WL7AU)	20 mg in 10 mL
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	40 mg in 10 mL

EDETATE SODIUM (UNII: MP1J8420LU)	0.9 mg in 10 mL
GRAPEFRUIT (UNII: O82C39RR8C)	0.0048 mL in 10 mL
WATER (UNII: 059QF0K00R)	10 mL in 10 mL

Product Characteristics

Color		Score	
Shape		Size	
Flavor	grape	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65131-098-47	1 in 1 BOX	04/01/2017	
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	04/01/2017	

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(65131-098)

Revised: 3/2017

LABORATORIO MAGNACHEM INTERNATIONAL SRL