

**BRONCOCHEM KIDS COLD AND FLU- acetaminophen-phenylephrine hcl-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 KIDS COLD and FLU

Warnings

Liver warnings: this product contains acetaminophen; severe liver damage may occur if you take:

More than 4 doses in 24 hour, which is the maximum daily amount for this product.

With other drugs containing acetaminophen.

Sore throat warnings: if sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea or vomiting, consult a doctor promptly.

allergy warnings: acetaminophen may cause severe skin reactions; symptoms may include:

Skin reddening, blisters, rash. If skin reactions occur, stop use and seek medical attention.

Uses

Bronchial congestion, irritation of the respiratory passages, helps loosen phlegm (mucus) and dilute bronchial secretions, temporarily reduces fever and minor pains associated with cold, headache, and sore throat.

Active Ingredients

Acetaminophen.....325.00mg

Guaifenesin.....200.00mg

Phenylephrine HCl.....5.00mg

Ask a doctor before use if your kid have

Liver disease

Persistent or chronic cough, asthma or emphysema

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

Stop use and ask a doctor if

Symptoms last more than 5 days

Fever gets worse or lasts more than 3 days, or occurs with rash or headache that lasts, a persistent cough, this could be signs of a serious condition

If your child is taking the blood thinning drug warfarin

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 form 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 USP, Sucralose, Citric acid, disodium Hedta, Povidone, Sodium citrate dihydrate, Sodium chloride, Honey, Propyl gallate, FD&C Red #40, Aloe Vera, Methylparaben USP, Propylparaben USP, Bubble Gum flavor, Raspberry flavor, Nat. Masking type #27872, Purified water.

Questions?

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

Purose

Acetaminophen.....Analgesic

Guaifenesin.....Expectorant

Phenylephrine.....Decongestant

Package 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</p> <ul style="list-style-type: none"> ■ liver disease ■ persistent or chronic cough, asthma or emphysema ■ if your kid is allergic to acetaminophen or any other 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 ■ fever gets worst or last more than 3 days, or occurs with rash or headache that last, a persistent cough, this could be signs of a serious condition ■ if your child is taking the blood thinning drug warfarin <p>Keep out of the reach of children.</p> <p>Inactive ingredients Propylene glycol, glycerin, sorbitol 70% USP, sucralose, citric acid, disodium EDTA, povidone, sodium citrate dihydrate, sodium chloride, honey, propyl galate, Red color #40FD&C, aloe vera, metil paraben USP, propyl paraben USP, bubble gum flavor, raspberry flavor, NAT FL masking type #27372, purified water.</p>	<p>NDC 65131-098-44</p> <h1 style="margin: 0;">Broncochem®</h1> <h2 style="margin: 0; background-color: #76b82a; color: white; padding: 5px;">COLD & FLU SYRUP</h2> <p style="margin: 0;">Bronchial and nasal decongestant</p> <p style="margin: 0;">Pain and fever control</p> <p style="margin: 0;">Aloe with love</p> <div style="float: right; border: 2px solid #76b82a; border-radius: 50%; padding: 10px; color: white; font-weight: bold; font-size: 1.2em;">Kids</div>		<p>Active Ingredients (in 10 mL or cc)</p> <table border="0" style="width: 100%;"> <tr> <td style="width: 60%;">Acetaminophen</td> <td style="width: 20%;">325.00 mg</td> <td style="width: 20%; text-align: right;">Analgesic</td> </tr> <tr> <td>Guaifenesin USP</td> <td>200.00 mg</td> <td style="text-align: right;">Expectorant</td> </tr> <tr> <td>Phenylephrine HCl</td> <td>5.00 mg</td> <td style="text-align: right;">Decongestant</td> </tr> </table> <p>Uses Bronchial congestion, irritation of the respiratory passages, helps loosen phlegm (mucus) and dilute bronchial secretions, temporarily reduces fever and minor pains associated with cold, headache, and sore throat.</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%; border-collapse: collapse;"> <tr> <td style="width: 40%;">children from 6 to 12 years</td> <td style="width: 60%;">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> <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>	Acetaminophen	325.00 mg	Analgesic	Guaifenesin USP	200.00 mg	Expectorant	Phenylephrine HCl	5.00 mg	Decongestant	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
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<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 COLD AND FLU

acetaminophen-phenylephrine hcl-guaifenesin syrup

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65131-054
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg in 10 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 10 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 10 mL

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	1.5 mL in 10 mL
GLYCERIN (UNII: PDC6A3C0OX)	2.5 mL in 10 mL
SORBITOL (UNII: 506T60A25R)	2 mL in 10 mL
SUCRALOSE (UNII: 96K6UQ3ZD4)	15 mg in 10 mL
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	20 mg in 10 mL
DISODIUM HEDTA (UNII: KME849MC7A)	0.9 mg in 10 mL
POVIDONE K90 (UNII: RDH86HJV5Z)	100 mg in 10 mL
SODIUM CITRATE (UNII: 1Q73Q2JULR)	40 mg in 10 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	6.25 mg in 10 mL
HONEY (UNII: Y9H1V576FH)	100 mg in 10 mL

PROPYL GALLATE (UNII: 8D4SNN7V92)	1 mg in 10 mL
FD&C RED NO. 40 (UNII: WZB9127XOA)	0.16 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
RASPBERRY (UNII: 4N14V5R27W)	0.0048 mL in 10 mL
WATER (UNII: 059QF0K00R)	10 mL in 10 mL

Product Characteristics

Color		Score	
Shape		Size	
Flavor	BUBBLE GUM	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65131-054-18	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)

Revised: 4/2017

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