

**BRONCOCHEM COLD AND FLU TEA- acetaminophen-phenylephrine hydrochloride-  
chlorpheniramine maleate granule, for solution  
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 COLD AND FLU TEA**

**Warnings**

Liver warning:

This product contains acetaminophen, severe liver damage may occur if you take:

- More than 6 packets in 24 hours, which is the maximum daily amount.
- with other drugs containing acetaminophen.
- three (3) or more alcoholic drinks every day while using this product.

Sore Throat warning:

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.

**Active Ingredients**

Acetaminophen.

Phenylephrine Hydrochloride.

Chlorpheniramine Maleate

Purpose

Pain reliever/fever reducer

Nasal decongestant

Antihistamine

*Keep Out of the Reach of Children*

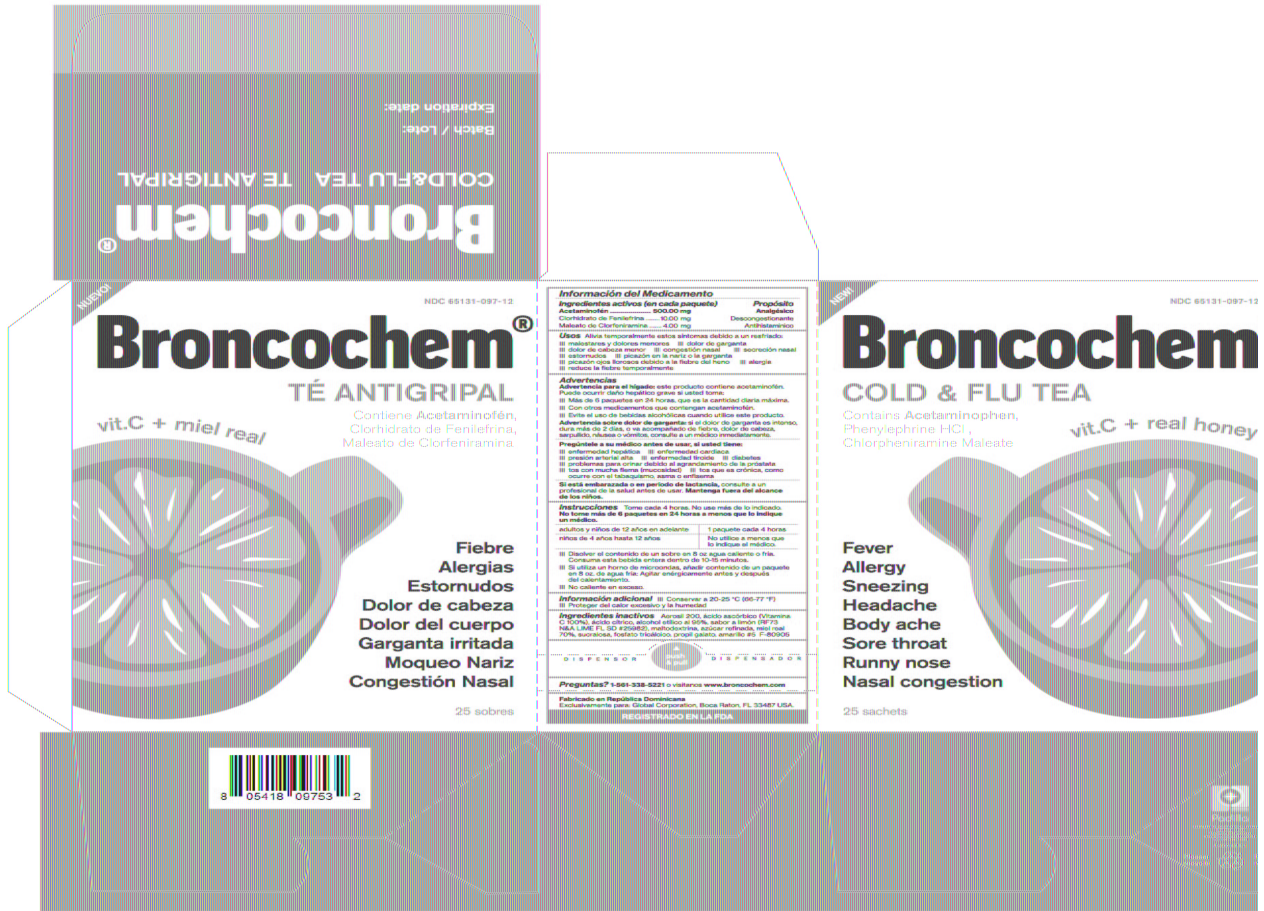
In case of overdose get medical help or contact a Poison Control Center right away, prompt medical attention is critical for adults as well as for children even if you do not notice any signs symptoms.

**Indications and Usage**

Temporarily relieves these symptoms due to a cold:

- Minor aches and pains.
- Minor sore throat pain.
- Headache.
- Nasal and sinus congestion.
- Runny nose.
- Sneezing
- Itchy nose or throat.
- Itchy, watery eyes due to hay fever.
- Cough due to minor throat and bronchial irritation.
- Temporarily reduces fever.





BOX IMAGE



## BRONCOCHEM COLD AND FLU TEA

acetaminophen-phenylephrine hydrochloride-chlorpheniramine maleate granule, for solution

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65131-097
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg in 13 g
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:V1Q0O9OJ9Z)	CHLORPHENIRAMINE	4 mg in 13 g

UNII:3U6IO1965U)

MALEATE

4 mg in 13 g

**Inactive Ingredients**

Ingredient Name	Strength
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ)	10 mg in 13 g
ASCORBIC ACID (UNII: PQ6CK8PD0R)	66 mg in 13 g
SUCROSE (UNII: C151H8M554)	9483 mg in 13 g
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	1500 mg in 13 g
HONEY (UNII: Y9H1V576FH)	100 mg in 13 g
MALTODEXTRIN (UNII: 7CVR7L4A2D)	1000 mg in 13 g
TRICALCIUM PHOSPHATE (UNII: K4C08XP666)	166.6 mg in 13 g
SUCRALOSE (UNII: 96K6UQ3ZD4)	28.43 mg in 13 g
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	40 mg in 13 g
PROPYL GALLATE (UNII: 8D4SNN7V92)	0.433 mg in 13 g
ALCOHOL (UNII: 3K9958V90M)	0.001 mL in 13 g

**Product Characteristics**

Color	yellow (FD&C YELLOW NO.5)	Score	
Shape		Size	
Flavor	LIME (LIME (CITRUS))	Imprint Code	
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65131-097-53	6 in 1 BOX	09/28/2017	
1	NDC:65131-097-52	13 g in 1 PACKAGE; Type 0: Not a Combination Product		
2	NDC:65131-097-12	25 in 1 BOX	09/28/2017	
2	NDC:65131-097-52	13 g in 1 PACKAGE; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	09/01/2013	

**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(65131-097)