

BRONCOCHEM COLD AND FLU CAPLETS- acetaminophen-dextromethorphan hbr-phenylephrine hcl-chlorpheniramine maleate tablet, coated
LABOTORIO 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 COLD & FLU CAPLETS

Warnings

Unless directed by a physician do not take this product if persistent or chronic cough such as occurs with, smoking, asthma, chronic bronchitis, emphysema, or if cough is accompanied by excessive phlem (mucus). Likewise if you have heart disease, diabetes, or difficulty in urination due to enlargement of the prostate gland, do not take this product unless directed by a physician.

If nervousness, dizziness, or sleeplessness occurs, discontinue use or consult a doctor.

If symptoms do not improve within 7 days or are accompanied by fever, consult a doctor.

A persistent cough may be a sign of a serius condition. If cough or other symptoms persist or not improve with any drug, if you are pregnant or nursing a baby, seeh the advice of a health professional before using this product.

Unless directed by a doctor, do not take this product if you are presently taking another product containing pseudoephedryne HCl, or if you are taking this product precaution must be taken when driving a motor vehicle or operating machinery.

Active Ingredients

Acetaminofen

Dextromethorphan HBr

Phenylephryne HCL

Chlorpheniramine Maleate

Purpose

Analgesic

Antihistaminic

Antitussive

Descongestant

Keep Out Of The Reach Of Children

In case of accidental overdose, seek professional assistance or contact a poison control center immediately

Indications and Usage

Bronchial congestion, irritation of the respiratory passages, nasal congestion.

Antitussive, temporary relief of allergy symptoms including runny nose, sneezing, stuffy nose, itchy

nose, itchy throat, irritated and watery eyes, allergy rhinitis

Indications and Usage

Adults and children 12 years and over, take one tablet every 6 hours.

Do not exceed 4 doses in a 24 hour period

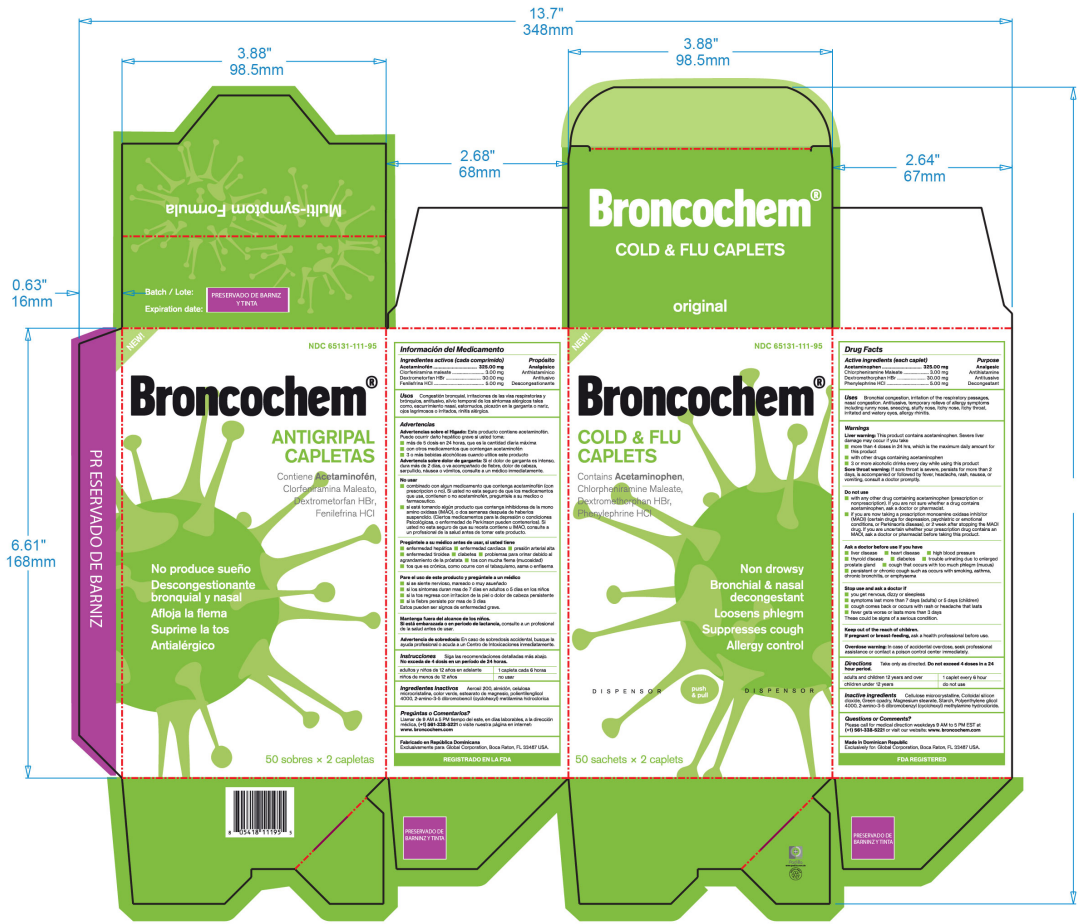
Drug Interactions

Do not use if you are taking a prescription monoamine oxidase inhibitor (MAOI), (Certain drugs for depression, psychiatric or emotional conditions, or Parkinsons disease) or for 2 weeks after stopping that MAOI drug, if you are uncertain whether your prescription drug contains an MAOI, consult a health professional before taking this product

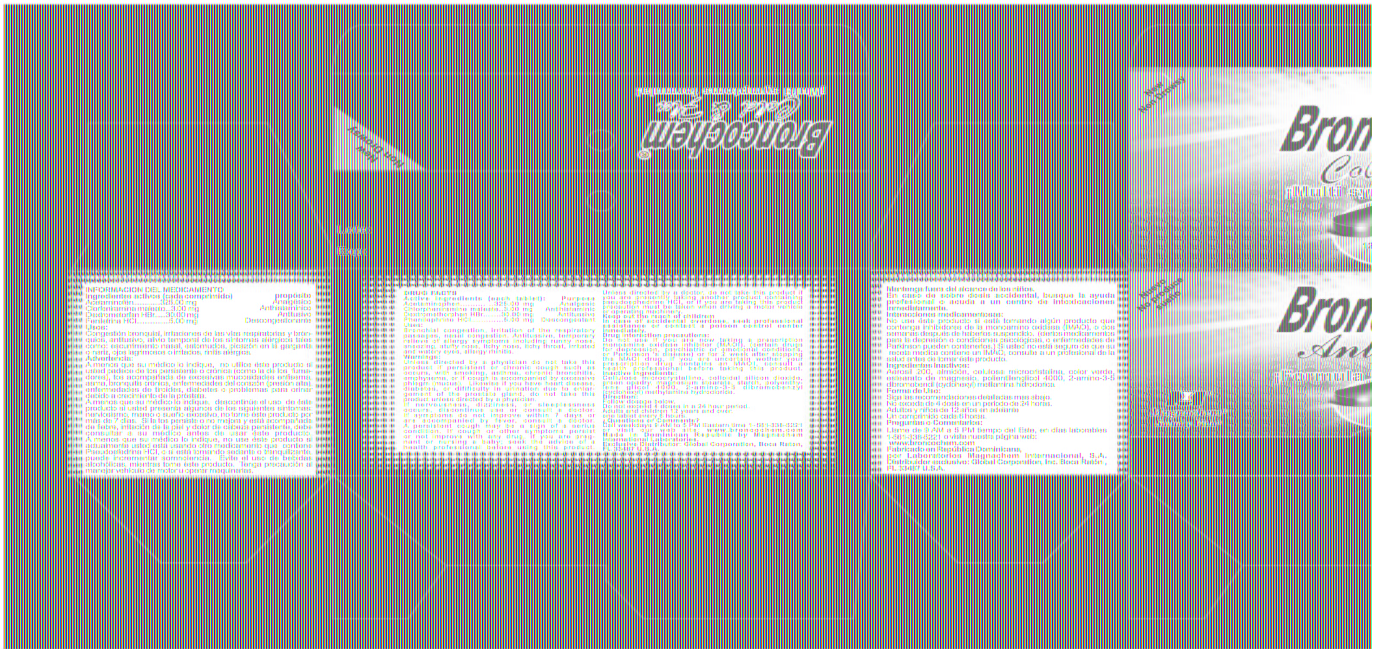
Inactive Ingredients

Cellulose Microcrystalline, Colloidal Silicon dioxide, Green Opadry, Magnesium Stearate, Pregelatinized Starch, PEG 4000

Package Label Principal Display Panel



Package Label Principal Display Panel



BRONCOCHEM COLD AND FLU CAPLETS

acetaminophen-dextromethorphan hbr-phenylephrine hcl-chlorpheniramine maleate tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65131-111
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	5 mg
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	3 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D6IU)	250 mg
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	142 mg
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	2 mg
MAGNESIUM STEARATE (UNII: 70097M6I30)	2.8 mg

PEG-80 STEARATE (UNII: 1X2OAT3BFK)			1.6 mg	
Product Characteristics				
Color	green	Score	no score	
Shape	capsule	Size	18mm	
Flavor		Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65131-111-21	12 in 1 BOX	12/30/2016	
1	NDC:65131-111-95	50 in 1 BOX		
1		2 in 1 POUCH; 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	01/01/2010		

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(65131-111)

Revised: 12/2016

LABOTORIO MAGNACHEM INTERNATIONAL SRL