BRONCOCHEM MAXIMUM COUGH NIGHT- dextromethorphan hbr-pyrilamine maleate syrup LABORATORIO MAGNACHEM INTERNATIONAL SRL

Broncochem Maximum Cough Night

Warnings

The following side effects may occur, nausea, vomiting, dizziness, headache, or nervousness may occur, if any of these effects last or worsen, contact your doctor or pharmacist immediately. Stop using this medicine and tell your doctor right away if you have dizziness, nervousness, or trouble sleeping.

OTC-PURPOSE SECTION

Antitussive

Antihistamine

OTC - Active Ingredient Section

Dextromethorphan HBr

Mepyramine maleate

Uses

Temporarily relieves these symptoms in all formsof acute, subacute, and cronical cough of any origin, it is very effective in colds, rhinitis, pharyngitis, laryngitis, dry cough, smokers cough, ashma, nervous cough.

Do Not Use

Stop using this medicine and contact your doctor right away if any of these unlikely but serious side effects occur, fast and irregular heartbeat, mental mood changes such as confusion, hallucinations, nervousness, seizures, tremor, problems with to pee.

If you are taking any monoamine oxidase inhibitor (MAOI), or two weeks after stopping them (certain medications for depression or psycological conditions may contain them). If you are not sure if your prescription contains an MAOI, coinsult a professional of health before taking this product.

Ask a doctor/pharmacist

Ask a doctor before use if yoy have

Liver disease, heart disease, high blood pressure, thyroid disease, diabetes, trouble urinating due to enlarged prostate gland, cough that occurs with too much phlegm

(mucus), presistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema.

Stop use and ask a doctor if

Symptoms last more than 7 days, symptoms worsen or come back, you develop a headache that wont go away, fever, or skin rash. If pregnant or breast-feeding ask a health professional before use.

Keep Out of the Reach of Children

In case of accidental overdose, seek professional help or go to poison control center immediately.

Dosage and Administration

Do not exceed 4 doses in a 24 hour period.

Adult and children 12 years and older: 10 mL 3-4 times a day.

Children 6 to under 12 years old: 5 mL 3-4 times a day.

Inactive Ingredient

Sugar, Sodium Benzoate, FD&C Yellow #5, Orange flavor, MEthyl paraben, Propyl paraben, ethyl alcohol 95%, Sorbitol 70%, Purified water.

PACKAGE LABEL PRINCIPAL DISPLAY PANEL













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Stop use and ask a doctor if

- Symptoms last more than 7 days
- If symptoms worsen or come back
- If you develop a headache that won't go away, fever, or skin rash.

If pregnant or breast-feeding, ask a health professional before use

Keep out of the reach of children.

Overdose warning: In case of accidental overdose, seek professional help or go to a Poison Control Center immediately.

Other information Store at no more than 30°C (86°F) Do not use if security cap is altered or broken

This product contains alcohol and sugar.

Inactive ingredients Refined sugar, Sodium benzoate, Yellow #5 color, Orange flavor, Methyl paraben, Propyl paraben, Ethyl alcohol 95%, Sorbitol 70%, Purified water.

Broncochem

MAXIMUM COUGH

NIGHT

Relieves cough of all origins Powerful cough suppressant to help you sleep at night Contains Alcohol & Sugar

Made in Dominican Republic Exclusively for: Global Corporation Inc., Boca Raton, FL 33487 U.S.A.

Lote / Batch:

Active ingredients (in each 10 mL)

Mepyramine maleate 50.00 mg Antihistamine Dextromethorphan HBr 30.00 mg Antitussive

Purpose

Uses Temporarily relieves these symptoms in all forms of acute, subacute, and conical cough of any origin, it is very effective in colds, rhinitis, pharyngitis, laryngitis, dry cough, smokers' cough, asthma, nervous cough

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Liver disease, heart disease, high blood pressure, thyroid disease, diabetes, trouble urinating due to enlarged prostate gland, cough that occurs with too much phlegm (mucus), persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema.

Directions Take only as directed. For your convenience, a dosage spoon is provide. **Do not exceed 4 doses in a 24 hour period.**

Adults and children 12 years and older Children between 6 to 12 years old

10 mL 3 or 4 times a day

5 mL 3 or 4 times a day

See carton for complete information for use.

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**

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BRONCOCHEM MAXIMUM COUGH NIGHT

dextromethorphan hbr-pyrilamine maleate syrup

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65131-110	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 5 mL	
PYRILAMINE MALEATE (UNII: R35D29L3ZA) (PYRILAMINE - UNII:HPE317O9TL)	PYRILAMINE MALEATE	50 mg in 5 mL	

Inactive Ingredients			
Ingredient Name	Strength		
SUGARCANE (UNII: 81H2R5AOH3)	2.65 mg in 5 mL		
SODIUM BENZOATE (UNII: OJ245FE5EU)	10 mg in 5 mL		
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	0.25 mg in 5 mL		
ORANGE OIL (UNII: AKN3KSD11B)	0.833 mg in 5 mL		
METHYLPARABEN SODIUM (UNII: CR6K9C2NHK)	5 mg in 5 mL		
PROPYLPARABEN SODIUM (UNII: 625NNB0G9N)	1.5 mg in 5 mL		
ALCOHOL 95% (UNII: 7528N5H79B)	0.25 mL in 5 mL		
SORBITOL SOLUTION 70% (UNII: 8KW3E207O2)	0.083 mL in 5 mL		
water (UNII: 059QF0KO0R)	5 mL in 5 mL		

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65131- 110-35	1 in 1 BOX	04/21/2025	
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 Drug	М	04/21/2025	

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(65131-110)	

Revised: 3/2025 LABORATORIO MAGNACHEM INTERNATIONAL SRL