

BRONCOCHEM MAXIMUM COUGH NIGHT- dextromethorphan hbr-pyrimilamine 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 forms of acute, subacute, and chronic cough of any origin, it is very effective in colds, rhinitis, pharyngitis, laryngitis, dry cough, smokers cough, asthma, 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 psychological conditions may contain them). If you are not sure if your prescription contains an MAOI, consult a professional of health before taking this product.

Ask a doctor/pharmacist

Ask a doctor before use if you 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), persistent 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 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

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: (5 or 10 mL) 3 times a day.

Children between 6 to 12 years old: (2.5 mL) 3 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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PACKAGE LABEL PRINCIPAL DISPLAY PANEL



BRONCOCHEM MAXIMUM COUGH NIGHT

dextromethorphan hbr-pyrimamine maleate syrup

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65131-035
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg in 5 mL

PYRILAMINE MALEATE (UNII: R35D29L3ZA) (PYRILAMINE - UNII:HPE317O9TL) PYRILAMINE MALEATE 6 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:65131-035-80	1 in 1 BOX	02/09/2024	
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 M		02/09/2024	

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(65131-035)

Revised: 4/2024

LABORATORIO MAGNACHEM INTERNATIONAL SRL