LIMPIA PECHO- dextromethorphan hbr, guaifenes in liquid Llorens Pharmaceutical International Division, Inc.

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.

In each teaspoonful, 5 mL

Dextromethorphan HBr - 10 mg

Guaifenesin - 100 mg

Purpose

©Cough Suppressant

Expectorant

Uses

- temporarily relieves cough as may occur with the common cold
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus

Warnings

Do not exceed recommended dosage

Do not use

• if you are now taking a monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease) or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this prduct.

Ask a doctor before use if you have

- a cough that is accompanied by excessive phlegm (mucus)
- a persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema.

Stop use and ask a dotor if

• cough persist for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache. These may be signs of a serious condition

IIf pregnant or breast-feeding Dask a health professional before use.

Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center right away.

Directions

- use dosage cup provided
- Do not exceed 6 doses in any 24 hour period or as directed by a doctor

Age	Dose
Adults and children over 12 years of age	10 mL (2 tsp) every 4 hours
Children 6 to under 12 years of age	5 mL (1 tsp) every 4 hours
Children under 6	Ask a doctor

Inactive ingredients Dartificial and natural flavor, citric acid, methol, methylparaben, propylened glycol, propylparaben, purified water, sodium citrate, and sucralose.

Questions or Comments? 1-866-595-5598



LIMPIA PECHO

dextromethorphan hbr, guaifenesin liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54859-011
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
(DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 5 mL	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL	

Inactive Ingredients			
Ingredient Name	Strength		
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)			
MENTHOL (UNII: L7T10EIP3A)			
METHYLPARABEN (UNII: A2I8 C7HI9 T)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
PROPYLPARABEN (UNII: Z8IX2SC1OH)			
WATER (UNII: 059QF0KO0R)			
SODIUM CITRATE (UNII: 1Q73Q2JULR)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54859-011-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2019	
N	Iarketing Inf	ormation		
	Tarketing Info		Marketing Start Date	Marketing End Date
N		y Application Number or Monograph Citation	Marketing Start Date 05/01/2019	Marketing End Date

Labeler - Llorens Pharmaceutical International Division, Inc. (037342305)

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