

**TUSNEL COUGH SUPPRESSANT EXPECTORANT- dextromethorphan hbr,
guaifenesin 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 5 mL

Dextromethorphan - 10 mg

Guaifenesin - 100 mg

Purpose

Cough Suppressant

Expectorant

Uses

- temporarily relieves cough due to minor throat and bronchial irritation
- helps loosen phlegm (mucus)
- helps thin bronchial secretions to make coughs more productive

Warnings

Do not use if you are now taking a prescription monamine 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 product.

Do not use if you have ever had an allergic reaction to any of the ingredients in this product.

Ask a doctor before use if you have

- cough that occurs with too much phlegm (mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis, or emphysema

Stop use and ask a doctor if cough lasts for more than 7 days, comes back, or is accompanied by fever, rash, or head that lasts. These could be signs of a serious condition.

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

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions:

- take every 4 hours as needed, or as directed by a doctor
- do not take more than 6 doses in 24 hours
- do not exceed recommended dose

Age	Dose
Adults and children over 12 years and over	2 teaspoonfuls (10 mL)
Children under 12 years	do not use

Inactive ingredients cherry flavor, citric acid, FD&C #40, menthol, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate, sucralose, sucrose.

Questions or comments? 1-866-595-5598

NDC: 54859-509-16



Drug Facts

Active Ingredients (per 5 mL teaspoonful)

Dextromethorphan HBr, USP 10mg	Cough Suppressant
Guaifenesin, USP 100mg	Expectorant

Uses

temporarily relieves cough due to minor throat and bronchial irritation - helps loosen phlegm (mucus) - helps thin bronchial secretions to make coughs more productive

Warnings

Do not use if you are now taking a prescription 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 your doctor or pharmacist before taking this product.

Do not use if you have ever had an allergic reaction to any of the ingredients in this product.

Ask a doctor before use if you have

a cough with too much phlegm (mucus) - a cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis or emphysema.

Stop use and ask a doctor if cough lasts more than 7 days, comes back or is accompanied by fever, rash, or headache that lasts. These could be signs of a serious condition.

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

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

COUGH SUPPRESSANT EXPECTORANT

Oral Solution

**Guaifenesin
Dextromethorphan** **CHERRY FLAVOR**

✓ Controls Cough
✓ Loosens and Relieves Chest Congestion
✓ Alcohol Free

Compare to the active ingredients in Robitussin® DM*

16 FL OZ (473 mL)

Drug Facts (continued)

DIRECTIONS

- take every 4 hours as needed, or as directed by a doctor
- do not take more than 6 doses in 24 hours
- do not exceed recommended dose

Adults and children 12 years and over	2 teaspoonfuls (10 mL)
Children under 12 years	do not use

OTHER INFORMATION

- each teaspoonful (5 mL) contains: **sodium 2mg**
- store at room temperature 15°-30°C (59°-86°F)
- protect from freezing - do not refrigerate - protect from light
- Pharmacists-Preserve and dispense in a tight, light resistant container with a child resistant cap as defined in the USP
- TAMPER-EVIDENT:** Do not use if foil seal over bottle opening is torn broken or missing.

Inactive ingredients: cherry flavor, citric acid, FD&C Red #40, menthol, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate, sucralose, sucrose.

Questions or comments? 1-866-595-5598

*This product is not manufactured or distributed by the owner of the registered trademark Robitussin®DM.

THIS IS A BULK CONTAINER NOT INTENDED FOR DISPENSING

Manufactured by: Code #: L-159 Rev.: 05/22
Llorens Pharmaceutical International Division, Inc.
7080 NW 37th Court Miami, FL 33147 | www.LlorensPharm.com

Llorens Pharmaceutical

Lot #: _____
Exp Date: _____



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TUSNEL COUGH SUPPRESSANT EXPECTORANT

dextromethorphan hbr, guaifenesin liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54859-509
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 5 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
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ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MENTHOL (UNII: L7T10EIP3A)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SUCROSE (UNII: C151H8M554)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54859-509-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/01/2019	

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

Revised: 7/2022

Llorens Pharmaceutical International Division, Inc.