TUSNEL DIABETIC- dextromethorphan, guaifenes in liquid LLORENS PHARMACEUTICALS INTERNATIONAL DIVISION

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.

DRUG FACTS

Active Ingredients (in each 5 mL tsp.)	Purpose
Dextromethorphan HBr USP 10 mg	Cough Suppressant
Guaifenesin USP 100 mg	Expectorant

Purpose

©Cough Suppressant

Expectorant

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 if 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 giving this product.

Ask a doctor before use if you have

- a 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 last more than 7 days, comes back, or is accompanied by fever, rash or persistent headache. A persistent cough could b a sign of a serious condition.

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

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

Directions

Do not exceed more than 6 doses in any 24-hour period or as directed by a doctor.

Age	Dose
Adults and children 12 years of age and	2 teaspoonfuls (10 mL) every 4
over	hours
Under 2 years of age	Do not use

Uses

Temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold Helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive

Inactive Ingredients: anhydrous citric acid, flavor, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate dihydrate and sucralose.

Questions or Comments? 1-866-595-5598

Distributed By: Llorens International Division, Miami FL 33165

rug Facts

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..Cough Suppressant
......Expectorant

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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 a doctor or pharmacist before taking this product.

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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 right away.



Manufactured by:

MEMBERS ASSECTION

INTERNATIONAL DIVISION

MIAMI, FL 33147

WWW.Llorenspharm.com

MADE IN USA

NDC 54859-505-16

TUSNEL DIABETIC

- NO SUGAR NO SACCHARINE
- NO ALCOHOL NO DYE

Cough Suppressant/ Expectorant

APPLE BANANA
www.llorenspharm.com

CONTENTS: 16 FL OZ (473 ML)

Drug Facts (Continued)

Directions: Do not exceed more than 6 doses in any 24-hour period.

Age	Dose
Adults and children 12 years and over	2 teaspoonfuls (10 mL) every 4 hours
Children under 12 years	Ask a doctor

Other information: • store at controlled room temperature 15-30°C (59-86°F)•Do not use if foil over bottle opening is torn, broken, or missing.•Pharmacist- Preserve and dispense in tight light-resistant container with a child resistant cap as defined in the USP.

Inactive ingredients anhydrous citric acid, flavor, methylparaber propylene glycol, propylparaben, purified water, sodium citrate dihydrate, and sucralose.

Questions or comments? 1-866-595-5598

THIS IS A BULK CONTAINER NOT INTENDED FOR DISPENSING

Code#L-48 Rev.: 07/1

Lot#

Exp. Date

TUSNEL DIABETIC

dextromethorphan, guaifenesin liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:54859-505

Route of Administration ORAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) DEXTROMETHORPHAN HYDROBROMIDE 10 mg in 5 mL GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) GUAIFENESIN

Inactive Ingredients		
Ingredient Name	Strength	
SUCRALOSE (UNII: 96K6UQ3ZD4)		
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)		
METHYLPARABEN (UNII: A2I8C7HI9T)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
PROPYLPARABEN (UNII: Z8IX2SC1OH)		
WATER (UNII: 059QF0KO0R)		
SODIUM CITRATE (UNII: 1Q73Q2JULR)		

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	GRAPE (grape flavor)	Imprint Code	
Contains			

	Packaging				
ı	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1	NDC:54859-505-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2003	
	2	NDC:54859-505-16	472 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2003	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	12/01/2003	

Labeler - LLORENS PHARMACEUTICALS INTERNATIONAL DIVISION (037342305)

Revised: 11/2017 LLORENS PHARMACEUTICALS INTERNATIONAL DIVISION