

TUSNEL PEDIATRIC DM- dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid

Llorens Pharmaceutical International Division, Inc.

Llorens-Tusnel DM Ped 604

In each 5 mL

Dextromethorphan HBr - 5 mg

Guaifenesin - 75 mg

Phenylephrine HCl - 2.5 mg

Purpose

Cough Suppressant

Expectorant

Nasal Decongestant

Uses

- temporary relieves cough due to minor throat and bronchial irritations as may occur with the common cold or inhaled irritants
- helps loosen phlegm (mucus) and thin bronchial secretions to make cough more productive
- temporarily relieves nasal congestion due to the common cold

Warnings

Do not use if your child is 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 child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

Ask a doctor before use if your child has

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- difficulty in urination due to enlargement of prostate gland
- a cough with too much phlegm (mucus)
- a persistent or chronic cough as occurs with smoking, asthma, chronic bronchitis, or emphysema

Ask a doctor before use if your child is

- taking sedatives, tranquilizers or drugs for depression or MAOI drugs.

Stop use and ask a doctor if your child gets

- nervousness, dizziness, or sleeplessness occur
- cough lasts for more than 7 days, comes back or occurs with a fever, rash or headache that lasts. These could be signs of a serious condition.

If pregnant or breast-feeding, ask a doctor before use

Keep out of reach of children. In case of accidental overdose, seek advice of a doctor or contact a Poison Control Center right away.

Directions: Do not exceed 6 doses in 24 hour

Age	Dose
Children 6 to under 12 years of age	Take 2 teaspoonful (10 mL) every 4 hours
Children 2 to under 6 years of age	Take 1 teaspoonful (5 mL) every 4 hours
Children under 2 years of age	Ask a doctor

Inactive ingredients: artificial and natural flavor, citric acid, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate, and sucralose.

Questions or Comments? 1-866-595-5598

Drug Facts

Active ingredients (in each 5 mL tsp.)

Dextromethorphan HBr, USP.....5 mg.....Cough Suppressant

Guaifenesin, USP.....75 mg.....Expectorant

Phenylephrine HCl, USP.....2.5 mg.....Nasal Decongestant

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NDC 54859-604-16

TUSNEL[®] DM

PEDIATRIC

- Cough Suppressant
- Expectorant
- Nasal Decongestant
- Cotton Candy Flavor

Sugar **Free** • Dye **Free**
Alcohol **Free**

Manufactured by:
LLORENS
Llorens Pharmaceutical
International Division
Miami, FL 33147
www.llorensparm.com

Drug Facts (continued)

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Other information Tamper-Evident Disclosure-Do not use if aluminum seal over bottle opening is torn, broken or missing. Store at controlled room temperature | 5°-30°C (50°-86°F) Pharmacist- Preserve and dispense in tight, light-resistant container with a child resistant cap as defined in the USP.

Inactive ingredients: artificial and natural flavor, citric acid, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate, and sucralose.

Questions or Comments? 1-866-595-5598

Code #: L-116 Rev.: 08/18

THIS IS A BULK CONTAINER NOT INTENDED FOR DISPENSING

Lot. #
Exp. Date:

TUSNEL PEDIATRIC DM

dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54859-604
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RT19KYH)	DEXTROMETHORPHAN	5 mg

(DEXTROMETHORPHAN - UNII:7355X3ROTS)	HYDROBROMIDE	in 5 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	75 mg in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	2.5 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54859-604-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	05/01/2019	

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

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

Establishment

Name	Address	ID/FEI	Business Operations
Llorens Pharmaceutical International Division, Inc.		037342305	manufacture(54859-604)

Revised: 12/2025

Llorens Pharmaceutical International Division, Inc.