

TUSNEL PEDIATRIC DM- dextromethorphan hbr, guaifenesin, phenylephrine hcl 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 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.) **Purpose**

Dextromethorphan HBr, USP5 mgCough Suppressant

Guaifenesin, USP75 mgExpectorant

Phenylephrine HCl, USP2.5 mgNasal 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 has •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.

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

16 FL OZ (473 mL)

Drug Facts (continued)

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

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Children under 2 years of age	Ask a doctor

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 (59°-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: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg 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: 059QF0K00R)	
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 final	part341	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: 6/2019

Llorens Pharmaceutical International Division, Inc.