TUSNEL-DM PEDIATRIC- dextromethorphan hbr, guaifenesin, phenylephrine hcl solution/ drops
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.

Active Ingredients in each (1 mL)

Dextromethorphan HBr 2.5 mg

Guaifenesin 25 mg

Phenylephrine HCl 1.25 mg

Purpose

Cough suppressant

Expectorant

Nasal Decongestant

Uses

- Temporary relief of cough due to minor throat and bronchial irritation
- Temporarily relieves nasal congestion due to the common cold and thin bronchial secretions to make coughs more productive
- Helps loosen phlegm (mucus) and thin bronchial secretions to make cough more productive.

Warnings

Do not use in child whos is 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 child's prescription drug contains an MAOI: ask your doctor or pharmacist before giving this product.

Ask a doctor before use if your child has

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- a cough that occurs with too much phlegm
- a persistent or chronic cough that occurs with asthma, or if cough is accompanied by excessive phlegm (mucus) unless directed by a doctor.

When using this product

- **do not exceed the recommended dosage.**

Stope use and ask doctor if

- nervousness, dizziness or sleeplessness occurs
- symptoms do not get better within 7 days or accompanied by fever
- cough lasts more than 7 days, comes back, or is accompanied by fever, rash or persistent headache. A persistent cough may be a sign of a serious condition.

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

Directions

Do not exceed more than 4 doses in any 24-hour period or as directed by a doctor.

Age	Weight	Dose
Children 2 to under 6 years of age	24-47 lbs	Take 2 mL every 4-6 hours
Children under 2 years of age	Under 24 lbs	Ask a doctor

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

Questions or Comments? 1-866-595-5598

TUSNEL-DM PEDIATRIC

dextromethorphan hbr, guaifenesin, phenylephrine hcl solution/ drops

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54859-606
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	2.5 mg in 1 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	25 mg in 1 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	1.25 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**

ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
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:54859-606-01	30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	08/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/01/2019	

Labeler - LLORENS PHARMACEUTICALS INTERNATIONAL DIVISION (037342305)

Revised: 12/2019 LLORENS PHARMACEUTICALS INTERNATIONAL DIVISION