

TUSNEL DM PEDIATRIC- dextromethorphan, guaifenesin, pseudoephedrine hcl solution/ drops

Llorens Pharmaceutical International Division

Llorens-Tusnel DMPedDrops 603

Active Ingredients in each 1 mL (dropperful)	Purpose
Dextromethorphan HBr..... 2.5 mg.....	Cough suppressant
Guaifenesin.....25mg.....	Expectorant
Pseudoephedrine HCl.....7.5mg.....	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 who 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 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
- a cough that occurs with too much phlegm (mucus)
- a persistent or chronic cough such as occurs with asthma

When using this product

- do not exceed recommended dosage

Stop use and ask a doctor if

- nervousness, dizziness or sleeplessness occurs

- symptoms do not get better within 7 days or accompanied by fever
- cough last more than 7 days, comes back, or is accompanied by fever, rash or persistent headache. A persistent cough could be a sign of a serious condition.

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

Other information

- store at controlled room temperature 20° - 25° C (68° - 77° F); excursions permitted to 15° - 30° C (59° - 86° F) [See USP Controlled Room Temperature]
- Tamper evident by imprinted heat seal under cap. Do not use if there is evidence of tampering
- Oral dosing device enclosed

Inactive ingredients citric acid, D and C Red Number 33,FD and C Blue #1, flavor, glycerin, propylene glycol, sodium benzoate, sodium saccharin, water.

Questions or Comments? 1-866-595-5598

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 (two dropperfuls) every 4 to 6 hours
Children under 2 years of age	Under 24 lbs	ask a doctor

NDC 54859-603-02

TUSNEL DM

PEDIATRIC DROPS

- COUGH SUPPRESSANT
- NASAL DECONGESTANT
- EXPECTORANT



Manufactured for:
LLORENS
 International Division
 Miami, FL 33166
 www.Llorenspharm.com

NET CONTENT: 60 mL (2 FL. OZ.)

Drug Facts

Active ingredients in each 1mL (dropperful)	Purpose
Dextromethorphan HBr, USP 2.5 mg	Cough suppressant
Guaifenesin, USP 25 mg	Expectorant
Pseudoephedrine HCl, USP..... 7.5 mg	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 who 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.

Stop use and ask a 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 of 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 2mL (two dropperfuls) every 4-6 hours
Children under 2 years of age	Under 24 lbs	Ask a doctor

Other information ■ Store at controlled room temperature 20°-25°C (68°-77°F); excursions permitted to 15°-30°C (59°-86°F) (See USP Controlled Room Temperature) ■ Tamper evident: Do not use this product if printed inner cap seal is broken or missing ■ Oral dosing device enclosed.

Inactive ingredients: citric acid, D&C Red #33, FD&C Blue #1, flavor, glycerin, propylene glycol, sodium benzoate, sodium saccharin, water.

Questions or Comments? 1-866-595-5598

TUSNEL DM PEDIATRIC

dextromethorphan, guaifenesin, pseudoephedrine hcl solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54859-603
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	25 mg in 1 mL
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	7.5 mg in 1 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	2.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54859-603-02	60 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	01/01/1993	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	01/01/1993	

Labeler - Llorens Pharmaceutical International Division (037342305)

Revised: 12/2025

Llorens Pharmaceutical International Division