

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

**Llorens Pharmaceutical 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**

<b>Active Ingredients in each 1 mL (dropperful)</b>	<b>Purpose</b>
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.**

<b>Age</b>	<b>Weight</b>	<b>Dose</b>
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.llorensparm.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**

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

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

Ingredient Name	Strength
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>D&amp;C RED NO. 33</b> (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 final	part341	01/01/1993	

**Labeler** - Llorens Pharmaceutical International Division (037342305)

Revised: 12/2020

Llorens Pharmaceutical International Division