

**TUSNEL PEDIATRIC - 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.*

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**Drug Facts**

| <b>Active Ingredients in each 1 mL (dropperful)</b> | <b>Purpose</b>     |
|---|--------------------|
| Guaifenesin.....25mg.....                           | Expectorant        |
| Pseudoephedrine HCl.....7.5mg.....                  | Nasal Decongestant |

**Uses**

- temporarily relieves these symptoms due to the common cold and thin bronchial secretions to make coughs 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.

**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                                   |

### 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

**Drug Facts (continued)**  
**Directions:** Do not exceed more than 4 doses in any 24-hour period or as directed by a doctor.

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|--------------------------------------|--------------|--|
| Children 2 to under six years of age | 24-47 lbs    | Take 2mL (two dropperfuls) every 4-6 hours |
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**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 if imprinted 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

**Drug Facts**  
**Active Ingredients in each 1mL (dropperful) Purpose**  
 Guaifenesin USP ..... 50mg ..... Expectorant  
 Pseudoephedrine HCl, USP ..... 7.5mg ..... Nasal Decongestant

**Uses**  
 ■ Temporarily relieves nasal congestion due to the common cold and thin bronchial secretions to make coughs 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 (mucus)  
 ■ a cough that lasts or is chronic such as occurs with asthma.

**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.

## TUSNEL PEDIATRIC

guaifenesin, pseudoephedrine hcl solution/ drops

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:54859-602 |
| <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<br>in 1 mL  |
| <b>PSEUDOEPHEDRINE HYDROCHLORIDE</b> (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F) | PSEUDOEPHEDRINE<br>HYDROCHLORIDE | 7.5 mg<br>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 DIHYDRATE</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:54859-602-02 | 60 mL in 1 BOTTLE, DROPPER |                      |                    |

**Marketing Information**

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part341                                  | 01/01/2006           |                    |

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

Revised: 1/2013

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