

TUSNEL PEDIATRIC DROPS- 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)

Guaifenesin 25 mg

Phenylephrine HCl 1.25 mg

□ Purpose

Expectorant

Nasal Decongestant

□ Uses

- 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 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
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Children 2 to under 6 years of age
 Children under 2 years of age

24-47 lbs
 Under 24 lbs

Take 2 mL every 4-6 hours
 Ask a doctor

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

Questions or Comments? 1-866-595-5598

Drug Facts

Active ingredients in each 1mL

Guaifenesin, USP	25mg	Expectorant
Phenylephrine HCl, USP	1.25mg	Nasal Decongestant

Uses ■ 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.

Code: L-37 Rev: 10/19

Drug Facts (continued)

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 every 4-6 hours
Children under 2 years of age	Under 24 lbs	Ask a doctor

Other information ■ Store at controlled room temperature 15°-30°C (59°-86°F); ■ Tamper evident: Do not use if aluminum foil over bottle opening is torn, broken, or missing. ■ Oral dosing device enclosed.

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

Questions or Comments? 1-866-595-5598

Manufactured by: L.L. CROSSBERG INTERNATIONAL DIVISION, INC. www.llorenspharm.com

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Lot. #
Exp. Date:

TUSNEL PEDIATRIC DROPS

guaifenesin, phenylephrine hcl solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54859-605
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
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:54859-605-01	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

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