

TUSNEL PEDIATRIC- dextromethorphan, guaifenesin, pseudoephedrine hcl liquid

Llorens Pharmaceutical International Division

Llorens-Tusnel Ped 544

Active Ingredients(in each 5 ml tsp.)

Purpose

Dextromethorphan HBr.....5mg.....	Cough Suppressant
Guaifenesin.....50mg.....	Expectorant
Pseudoephedrine HCl.....15mg.....	Nasal Decongestant

Purpose

Cough Suppressant

Expectorant

Nasal Decongestant

Warnings

Do not use if you are now 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 prescription drug contains an MAOI, ask a doctor or pharmacist before taking 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 6 to under 12 years of age	45 lbs to under 95 lbs	Take 2 teaspoonfuls (10 mL) every 4 to 6 hours
Children 2 to under 6 years of age	25 lbs to under 45 lbs	Take 1 teaspoonful (5mL) every 4 to 6 hours
Children under 2 years of age	Under 25 lbs	ask a doctor

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive
- temporarily relieves these symptoms occurring with a cold: nasal congestions, cough due to minor throat and bronchial irritation.

Inactive ingredients artificial and natural flavor, citric acid, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate, and sucralos

Questions or Comments? 1-866-595-5598

NDC 54859-544-16



**Alcohol FREE • Saccharin FREE
Dye FREE • Sugar FREE**

- Cough Suppressant
- Expectorant
- Nasal Decongestant

Grape

Manufactured by:
LLORENS
Llorens Pharmaceutical
International Division, Inc.
Miami, FL 33147
www.llorensparm.com



16 FL OZ (473 mL)

Drug Facts

Active ingredients (in each 5 mL tsp.)

Dextromethorphan HBr USP.....5 mg.....Cough Suppressant
Guaifenesin USP.....50 mg.....Expectorant
Pseudoephedrine HCl, USP.....15 mg.....Nasal Decongestant

Purpose

Expectorant

Uses ■ helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive ■ temporarily relieves these symptoms occurring with a cold: nasal congestion, cough due to minor throat and bronchial irritation

Warnings
Do not use in a 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 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.

Code #: L-80 Rev 11/17
THIS IS A BULK CONTAINER NOT INTENDED FOR DISPENSING.

Drug Facts (continued)

Keep out of reach of children. In case of overdose, get medical help or contact a Poison 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 6 to under 12 years of age	45 lbs to under 95 lbs.	Take 2 teaspoonfuls (10 mL) every 4 to 6 hours
Children 2 to under 6 years of age	25 lbs to under 45 lbs.	Take 1 teaspoonful (5mL) every 4 to 6 hours
Children under 2 years of age	Under 25 lbs	Ask a doctor

Other information ■ store at room temperature 15° to 30° C (59° to 86° F) ■ Tamper evident by heat seal under cap. Do not use if there is evidence of tampering.

Pharmacist Preserve and dispense in tight, light-resistant container with a child resistant cap as defined in the USP.

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

Questions or Comments? 1-866-595-5598



0 54859 54416 1

Lot. #

Exp. Date:

TUSNEL PEDIATRIC

dextromethorphan, guaifenesin, pseudoephedrine hcl liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54859-544
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 5 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	50 mg in 5 mL
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	15 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
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:54859-544-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2006	
2	NDC:54859-544-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2006	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	01/01/2006	

Labeler - Llorens Pharmaceutical International Division (037342305)