

TUSNEL- dextromethorphan, guaifenesin, pseudoephedrine hcl liquid
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

Active Ingredients (in each 5 ml tsp.)	Purpose
Dextromethorphan HBr.....15mg.....	Cough Suppressant
Guaifenesin.....200mg.....	Expectorant
Pseudoephedrine HCl.....30mg.....	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 you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- difficulty in urination due to enlargement of prostate gland
- a cough with too much phlegm (mucus)
- a persistent or chronic cough as occurs with smoking, asthma, chronic bronchitis, or emphysema

Ask a doctor before use if you are taking sedatives, tranquilizers or drugs for depression or MAOI drugs.

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- cough lasts for more than 7 days, comes back or occurs with a fever, rash or headache that lasts. These could be signs 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.

If pregnant or breast-feeding, ask a health professional before use.

Directions Do not exceed more than 4 doses in any 24-hour period or as directed by a doctor.

Age	Dose
Adults and children 12 years of age and over	Take 2 teaspoonfuls (10 mL) every 6 hours

Uses:

- temporarily relieves cough due to minor throat and bronchial irritation associated with the common cold
- helps control reflex that causes coughing
- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive
- temporarily relieves nasal congestion due to common cold, hay fever or other upper respiratory allergies (allergic rhinitis).

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

Questions or Comments? 1-866-595-5598

Drug Facts

Active ingredients (in each 5 mL tsp.)

Dextromethorphan HBr, USP15 mg Cough Suppressant

Guaifenesin, USP.....200 mg Expectorant

Pseudoephedrine HCl, USP.....30 mg Nasal Decongestant

Purpose

Uses: temporarily relieves cough due to minor throat and bronchial irritation associated with the common cold helps to control reflex that causes coughing helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive temporarily relieves nasal congestion due to common cold, hay fever or other upper respiratory allergies (allergic rhinitis).

Warnings

Do not use if you are taking a 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 using this product.

Ask a doctor before use if you have heart disease high blood pressure thyroid disease diabetes difficulty in urination due to enlargement of prostate gland a cough with too much phlegm (mucus) a persistent or chronic cough as occurs with smoking, asthma, chronic bronchitis, or emphysema

Ask a doctor before use if you are taking sedatives, tranquilizers or drugs for depression or MAOI drugs.

Stop use and ask a doctor if nervousness, dizziness, or sleeplessness occur cough lasts for more than 7 days, comes back or occurs with a fever, rash or headache that lasts. These could be signs of a serious condition.

Code #: L-62 Rev: 12/17

THIS IS A BULK CONTAINER NOT INTENDED FOR DISPENSING

NDC 54859-502-16



Sugar Free • Dye Free
Alcohol Free • Saccharin Free

- Cough Suppressant**
- Expectorant**
- Nasal Decongestant**

16 FL OZ (474 mL)

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



Drug Facts (continued)

If pregnant or breast-feeding, ask a health professional before use. **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	Dose
Adults and children 12 years of age and over	Take 2 teaspoonfuls (10 mL) every 6 hours

Other information store at room temperature 15° - 30°C (59° - 86°F). Tamper evident: Do not use if there is evidence of tampering.
Pharmacist: Preserve and dispense in light-light resistant container with a child resistant cap as defined in the USP.

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

Questions or Comments? 1-866-595-5598



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Lot. #
Exp. Date:

TUSNEL

dextromethorphan, guaifenesin, pseudoephedrine hcl liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54859-502
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg in 5 mL
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	200 mg in 5 mL
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	30 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
ASPARTAME (UNII: Z0H242BBR1)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
POTASSIUM CITRATE (UNII: EE90ONI6FF)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54859-502-06	178 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2006	
2	NDC:54859-502-16	474 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2006	
3	NDC:54859-502-10	3786 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 final	part341	01/01/2006	

Labeler - Llorens Pharmaceutical International Division (037342305)