#### TUSNEL C- codeine phosphate, guiafenesin, 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.

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#### **Drug Facts**

Active Ingredients (in each 5 ml tsp.)	P	urpose
Codeine Phosphate	10 mg	Cough Suppressant
Guaifenesin	100 mg	Expectorant
Pseudoephedrine HCl	30 mg	Nasal Decongestant

#### Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive
- temporarily relieves: nasal congestion due to the common cold, hay fever or other upper respiratory allergies and nasal congestion associated with sinusitis, cough due to minor bronchial irritation as may occur with the common cold
- temporarily restores freer breathing through the nose
- calms the cough control center and relieves coughing

### **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.

### When using this product

do nol exceed recommended dosage

• may cause or aggravate constipation

### Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- a breathing problem or persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema. chronic pulmonary disease or shortness of breath, or who are taking other drugs

#### Stop use and ask a doctor if

• you get nervous, dizzy or sleepless. symptoms do not get better within 7 days or are accompanied by fever. cough lasts more than 7 days, comes back, or is accompanied by fever, rash or persistant headache. These could be signs of a serious condition.

**Keep out of reach of children.** In case of overdose, get medical helpor contact a Poison Control Center right away.

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

**Directions: Follow dosage chart**Dosage may be repeated every 6 hours. Not to exceed 4 doses in 24-hours. Giving a higher dose

than recommended by a doctor could result in serious side effects for your child. A special measuring device should be used to give an accurate dose of this product to children under 6 years of age.

Age	Weight	Dose
children 12 years of age and over	95 lbs and up	Take 2 teaspoonfuls (10 mL) every 6 hours
Children 6 to under 12 years of age	45 lbs to under 95 lbs	Take 1 teaspoonful (5mL) every 6 hours
Children under 6 years of age	under 45 lbs	ask a doctor

#### Other information

- store at controlled room temperature 20°- 25°C (68°- 77°F)
- Each teaspoonful (5 ml) contains: sodium 2mg
- Tamper evident by imprinted heat seal under cap. Do not use if there is evidence of tampering.

**Inactive ingredients** aspartame, citric acid, glycerine, methylparaben, natural and artificial flavors, potassium citrate, potassium sorbate, propylene glycol, propylparaben, purified water.

**Questions or Comments?** 1-866-595-5598

NDC 54859-520-16 TAMPER-EVIDENT

# TUSNEL C (V

EXPECTORANT
NASAL DECONGESTANT
COUGH SUPPRESSANT
SUGAR-FREE
ALCOHOL-FREE

\*Under Federal law Tusnel C is available without a prescription. Certain State laws may differ.

#### **BULK CONTAINER - NOT FOR HOUSEHOLD USE.**

Dispense in a tight, light-resistant container as defined in the USP.



ONE PINT (473 mL)

#### Drug Facts

Active Ingredients (in each 5 ml tsp.)	Purpose
Codeine Phosphate	
	.30 mgNasal Decongestant

Uses = helps loosen philegm (mucus) and thin bronchial secretions to make coughs more productive = temporarily relieves; nasal congestion due to the common cold, hay fever or other upper respiratory allergies and nasal congestion associated with situstits, cough due to minor bronchial irritation as may occur with the common cold = temporarily restores freer breathing through the nose = calms the cough control center and relieves coughing

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Age	Weight	Dose
children 12 years and over	95 lbs and up	2 teaspoonfuls every 4 to 6 hours
children 6 to under 12 years of age	45 lbs to under 95 lbs	1 teaspoonfuls every 4 to 6 hours
children under 6 years of age	under 45 lbs	Consult a doctor

Other information - store at controlled room temperature 20°-25°C (68°-77°F)

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- \* Tamper Evident: Do not use this product if breakaway band on cap seal is broken or missing.

Inactive Impredients: ciric acid, FD&C Red #40, flavor, propylene glycol, sodium benzoate, sodium saccharin, sorbitol and water.

Questi'ons or comments: 1-866-595-5598

Distributed By: Llorens Pharmaceutical Corp, San Juan, P.R. 00926

Rev 11/0



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Rev 11/0



#### TUSNEL C

codeine phosphate, guiafenesin, pseudoephedrine hcl liquid

# Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:54859-520 Route of Administration ORAL DEA Schedule CV

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
<b>CODEINE PHO SPHATE</b> (UNII: GSL05Y1MN6) (CODEINE ANHYDROUS - UNII:UX6OWY2V7J)	CODEINE PHOSPHATE	10 mg in 5 mL		
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	100 mg in 5 mL		
<b>PSEUDO EPHEDRINE HYDRO CHLO RIDE</b> (UNII: 6 V9 V2RYJ8 N) (PSEUDO EPHEDRINE - UNII:7CUC9 DDI9 F)	PSEUDOEPHEDRINE HYDROCHLORIDE	30 mg in 5 mL		

Inactive Ingredients		
Ingredient Name	Strength	
FD&C RED NO. 40 (UNII: WZB9127XOA)		
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)		
SORBITOL (UNII: 506T60A25R)		
PROPYLENE GLYCOL (UNII: 6 DC9 Q16 7 V3)		
WATER (UNII: 059QF0KO0R)		

	Packaging				
l	#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
l	1	NDC:54859-520-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	0 1/0 1/19 9 5	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	0 1/0 1/19 9 5	

# Labeler - Llorens Pharmaceutical International Division (037342305)

Revised: 12/2020 Llorens Pharmaceutical International Division