TUSNEL- dextromethorphan hbr, guaifenesin, pseudoephedrine hcl tablet
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.

DRUG FACTS

Active Ingredients (In each tablet)		**Purpose**
Dextromethorphan HBr	30 mg	Cough Suppressant
Guaifenesin	400 mg	Expectorant
Pseudoephedrine HCl	60 mg	Nasal Decongestant

Uses

- temporarily relieves nasal congestion due to the common cold and thin bronchial secretions to make coughs more productive
- temporary relief of cough due to minor throat and bronchial irritation
- helps to control reflex that causes coughing

Warnings

Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- difficulty in urination due to the enlargement of the prostate gland
- a cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema. A persistent cough may be a sign of a serious condition.

When using this product do not exceed recommended dosage.

Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- 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

Do not use

- if you are now taking a prescription monamine 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 you are taking a prescription drug that contains on MAOI, ask your doctor or pharmacist before taking this product.

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.

adults and children 12 years of age and over	take 1 tablet every 6 hours
children 6 to under 12 years of age	take 1/2 tablet every 6 hours
children under 6 years of age	ask a doctor

Other Information

Store at controlled room temperature 20-25 degrees C (68-77 degrees F); excursions permitted to 15-30 degrees C (59-86 degrees F)

Tamper evident by imprinted heat seal under cap. Do not use if there is evidence of tampering

Inactive Ingredients: FD and C Blue No. 1, FD and C Blue No. 2, dicalcium phosphate, magnesium stearate, microcrystalline cellulose, purified water, sodium starch glycolate type B, titanium dioxide.

Questions or Comments? 1-866-595-5598

TUSNEL

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Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54859-801
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	60 mg

Inactive Ingredients	
Ingredient Name	**Strength**
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	

FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
WATER (UNII: 059QF0KO0R)	
SODIUM STARCH GLYCOLATE TYPE B POTATO (UNII: 27NA468985)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	white	**Score**	no score
Shape	OVAL	**Size**	20mm
Flavor		**Imprint Code**	TUSNEL
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54859-801-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2007	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/01/2007	

Labeler - LLORENS PHARMACEUTICALS INTERNATIONAL DIVISION (037342305)

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