TUSNEL PEDIATRIC - guiafenesin, pseudoephedrine hcl solution/ drops 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 e	ach 1 mL (dropperful)	Purpose
Guaifenesin	25mg	Expectorant
Pseudoephedrine HCl	7.5mg	Nasal Decongestant

Uses

• temporarily relieves these symptoms due to the common cold and thin bronchial secretions to make coughs 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 a 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.

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.

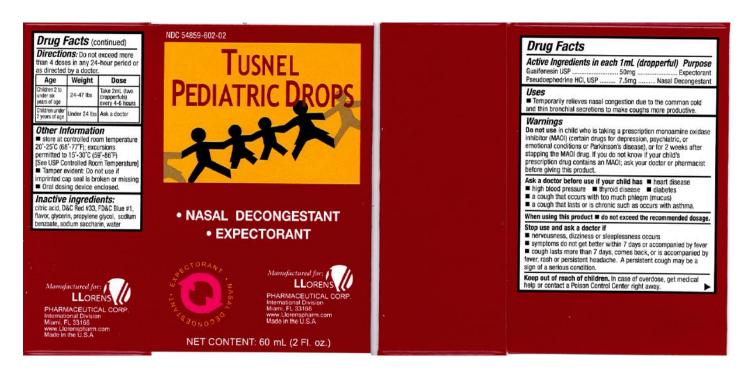
Age	Weight	Dose
Children 2 to under 6 years of age		Take 2 mL (two dropperfuls) every 4 to 6 hours
Children under 2 years of age	Under 24 lbs	ask a doctor

Other information

- store at controlled room temperature 20° 25° C (68° 77° F); excursions permitted to 15° 30° C (59° 86° F) [See USP Controlled Room Temperature]
- Tamper evident by imprinted heat seal under cap. Do not use if there is evidence of tampering
- Oral dosing device enclosed

Inactive ingredients citric acid, D and C Red Number 33,FD and C Blue #1, flavor, glycerin, propylene glycol, sodium benzoate, sodium saccharin, water.

Questions or Comments? 1-866-595-5598



TUSNEL PEDIATRIC

guiafenesin, pseudoephedrine hcl solution/ drops

Draduct Information			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54859-602
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	
PSEUDO EPHEDRINE HYDRO CHLO RIDE (UNII: 6 V9 V2RYJ8 N) (PSEUDO EPHEDRINE - UNII:7CUC9 DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	7.5 mg in 1 mL	

Inactive Ingredients		
Ingredient Name	Strength	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
CITRIC ACID MONO HYDRATE (UNII: 2968 PHW8 QP)		
GLYCERIN (UNII: PDC6A3C0OX)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SACCHARIN SO DIUM DIHYDRATE (UNII: SB8ZUX40TY)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
D&C RED NO. 33 (UNII: 9DBA0SBB0L)		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:54859-602-02	60 mL in 1 BOTTLE, DROPPER		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	0 1/0 1/20 0 6	

Labeler - Llorens Pharmaceutical International Division (037342305)

Revised: 1/2013 Llorens Pharmaceutical International Division