TUSNEL- dextromethorphan, guiafenes in, 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 HBr15mg | Cough Suppressant |
| Guaifenesin200mg | Expectorant |
| Pseudoephedrine HCl30mg | 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

- Theart 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

 \Box **Ask a doctor before use if you are** \Box 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 | Take 2 teaspoonfuls (10 mL) |
| 12 years of age and over | 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



TUSNEL

dextromethorphan, guiafenesin, 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: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 15 mg in 5 mL |
| Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ) | Guaifenesin | 200 mg in 5 mL |
| PSEUDO EPHEDRINE HYDRO CHLO RIDE (UNII: 6 V9 V2RYJ8 N) (PSEUDO EPHEDRINE - UNII:7CUC9 DDI9F) | PSEUDOEPHEDRINE HYDROCHLORIDE | 30 mg in 5 mL |

| Inactive Ingredients | | |
|--|----------|--|
| Ingredient Name | Strength | |
| ASPARTAME (UNII: Z0H242BBR1) | | |
| CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP) | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | |
| METHYLPARABEN (UNII: A2I8C7HI9T) | | |
| POTASSIUM CITRATE (UNII: EE90 O NI6 FF) | | |
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4) | | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | | |
| PROPYLPARABEN (UNII: Z8IX2SC1OH) | | |
| WATER (UNII: 059QF0KO0R) | | |
| | | |

|] | Packaging | | | |
|---|------------------|--|-----------------------------|---------------------------|
| 1 | # 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 | 0 1/0 1/20 0 6 | |
| 2 | NDC:54859-502-16 | 474 mL in 1 BOTTLE; Type 0: Not a Combination Product | 0 1/0 1/20 0 6 | |
| 3 | NDC:54859-502-10 | 3786 mL in 1 BOTTLE; Type 0: Not a Combination Product | 0 1/0 1/20 0 6 | |

| 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 | |
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$\pmb{Labeler-} \textbf{Llorens Pharmaceutical International Division (037342305)}$

Revised: 12/2020 Llorens Pharmaceutical International Division