

TRIPONEL- dextromethorphan hbr, pseufoephedrine hcl, triprolidine hcl liquid
Llorens Pharmaceutical International Division, Inc.

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.

Active Ingredients

□Dextromethorphan HBr
Pseudoephedrine HCl
Triprolidine HCl

Purpose

Cough Suppressant

Nasal Decongestant

Antihistamine

Uses

- □helps to control the reflex that causes coughing
- temporarily relieves nasal congestion due to common cold, hay fever, or other upper respiratory allergies (allergic: rhinitis)
- temporarily relieves these symptoms due to hay fever or upper respiratory allergies:
- runny nose
- itchy, watery eyes
- sneezing
- itching of the nose or throat

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 an enlargement of the 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.

□When using this product

- do not exceed recommended dose
- excitability may occur, especially in children
- drowsiness may occur
- avoid alcoholic beverages
- alcohol, sedative and tranquilizers may increase drowsiness

- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- nervousness, dizziness or sleeplessness occurs
- 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.

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 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
Children 6 to under 12 years of age	Take 1 teaspoonful (5mL) every 6 hours
Children under 6	Ask a doctor

Inactive ingredients artificial flavor, citric acid, glycerin, methylparaben, 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 mgCough Suppressant
Pseudoephedrine HCl, USP30 mgNasal Decongestant
Triprolidine HCl, USP1.25 mgAntihistamine

Purpose

Uses: ■ helps to control the reflex that causes coughing ■ temporarily relieves nasal congestion due to common cold, hay fever, or other upper respiratory allergies (allergic rhinitis) ■ temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ runny nose ■ itchy, watery eyes ■ sneezing ■ itching of the nose or throat

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.

When using this product ■ do not exceed recommended dose ■ excitability may occur, especially in children ■ drowsiness may occur ■ avoid alcoholic beverages ■ alcohol, sedatives and tranquilizers may increase drowsiness ■ be careful when driving a motor vehicle or operating machinery

Code #: L-91 Rev: 03/18

THIS IS A BULK CONTAINER NOT INTENDED FOR DISPENSING

NDC 54859-514-16

TriponeL

Sugar Free • Dye Free
Alcohol Free • Saccharin Free

- Cough Suppressant
- Nasal Decongestant
- Antihistamine

Cotton Candy Flavor

18 FL OZ (474 mL)

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



Drug Facts (continued)

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occurs
- 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.

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Children under 6	Ask a doctor

Other information ■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F). Tamper evident: Do not use if there is evidence of tampering.

Pharmacist: Preserve and dispense in tight-light resistant container with a child resistant cap as defined in the USP.

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

Questions or Comments? 1-866-595-5598



Lot. #
Exp. Date:

TRIPONEL

dextromethorphan hbr, pseudoephedrine hcl, triprolidine hcl liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54859-514
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
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	30 mg in 5 mL
TRIPROLIDINE HYDROCHLORIDE (UNII: YAN7R5L890) (TRIPROLIDINE - UNII:2L8T9S52QM)	TRIPROLIDINE HYDROCHLORIDE	30 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54859-514-16	474 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/01/2018	

Labeler - Llorens Pharmaceutical International Division, Inc. (037342305)

Revised: 12/2020

Llorens Pharmaceutical International Division, Inc.