TRIPONEL- dextromethorphan hbr, phenylephrine hcl, triprolidine hcl liquid
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.

Active Ingredients (in each 5 mL)

Dextromethorphan HBr 15 mg

Phenylephrine HCl 5 mg

Triprolidine HCl 1.25 mg

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 symptomes due to hay fever or ther upper respiratory allergies
- runny nose
- itchy, watery eyes
- sneexing
- 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 you r prescirption 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

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 beer, 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 a Poison Control Center right away.

Direcations: 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 (5 mL) every 6 hours
Children under 6	Ask a docotor

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

Questions or Comments? 1-866-595-5598

TRIPONEL

dextromethorphan hbr, phenylephrine hcl, triprolidine hcl liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54859-508
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
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	5 mg in 5 mL
TRIPROLIDINE HYDROCHLORIDE (UNII: YAN7R5L890) (TRIPROLIDINE - UNII:2L8T9S52QM)	TRIPROLIDINE HYDROCHLORIDE	1.25 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:54859-508-16	474 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/01/2019	

Labeler - LLORENS PHARMACEUTICALS INTERNATIONAL DIVISION (037342305)

Revised: 12/2019 LLORENS PHARMACEUTICALS INTERNATIONAL DIVISION