LORTUSS LQ- doxylamine succinate, pseudoephedrine hydrochloride liquid
Key Therapeutics

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.

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LORTUSS LQ LIQUID

Drug Facts

Active ingredients

(in each 5 mL teaspoonful) Doxylamine Succinate 6.25 mg Pseudoephedrine Hydrochloride 30 mg

Purpose

Antihistamine Decongestant

Uses

temporarily relieves these symptoms due to the common cold, hay fever (allergic rhinitis) or other upper respiratory allergies:

- runny nose
- itching of the nose or throat itchy, watery eyes
- nasal congestion
- reduces swelling of nasal passage

Warnings

Do not exceed recommended dosage.

Do not use this product

- 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

a breathing problem such as emphysema or chronic bronchitis especially in children glaucoma

trouble urinating due to an enlarged prostate gland heart disease

high blood pressure thyroid disease diabetes mellitus

Ask a doctor or pharmacist before use if you are

now taking sedatives or tranquilizers.

When using this product

- may cause excitability especially in children
- may cause marked drowsiness
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase the drowsiness effect
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- symptoms do not improve within 7 days or are accompanies by fever
- new symptoms occur

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of the reach of children.

In case of accidental overdose seek professional help or contact a Poison Control Center immediately.

Directions

Do not exceed recommended dosage.

Adults and children 12 years of age and older:	2 teaspoonfuls (10 mL) every 6 hours, not to exceed 8 teaspoonfuls in 24-hour period or as directed by a doctor.
Children 6 to under 12 years of age:	1 teaspoonful (5 mL) every 6 hours, not to exceed 4 teaspoonfuls in a 24-hour period or as directed by a doctor.
Children under 6 years of age:	Consult a doctor

Other information

Store at 59° - 86°F (15° - 30°C)

Inactive ingredients

Citric Acid, Glycerin, Grape Flavor, Methylparaben, Monoammonium Glycyrrhizinate, Potassium Citrate, Potassium Sorbate, Propylparaben, Propylene Glycol, Purified Water, Sucralose.

Questions? Comments?

Serious side effects associated with use of this product May be reported to this number. Call 1-888-981-8337

Mon - Fri (8 a.m. to 5 p.m. CST)

Principal Display Panel

NDC 70868-750-16 LORTUSS LQ

Antihistamine / Decongestant

Each 5 mL (1 teaspoonful) contains: Doxylamine Succinate……6.25 mg

Pseudoephedrine HCl……30 mg

Grape Flavor

Dye Free - Sugar Free - Alcohol Free

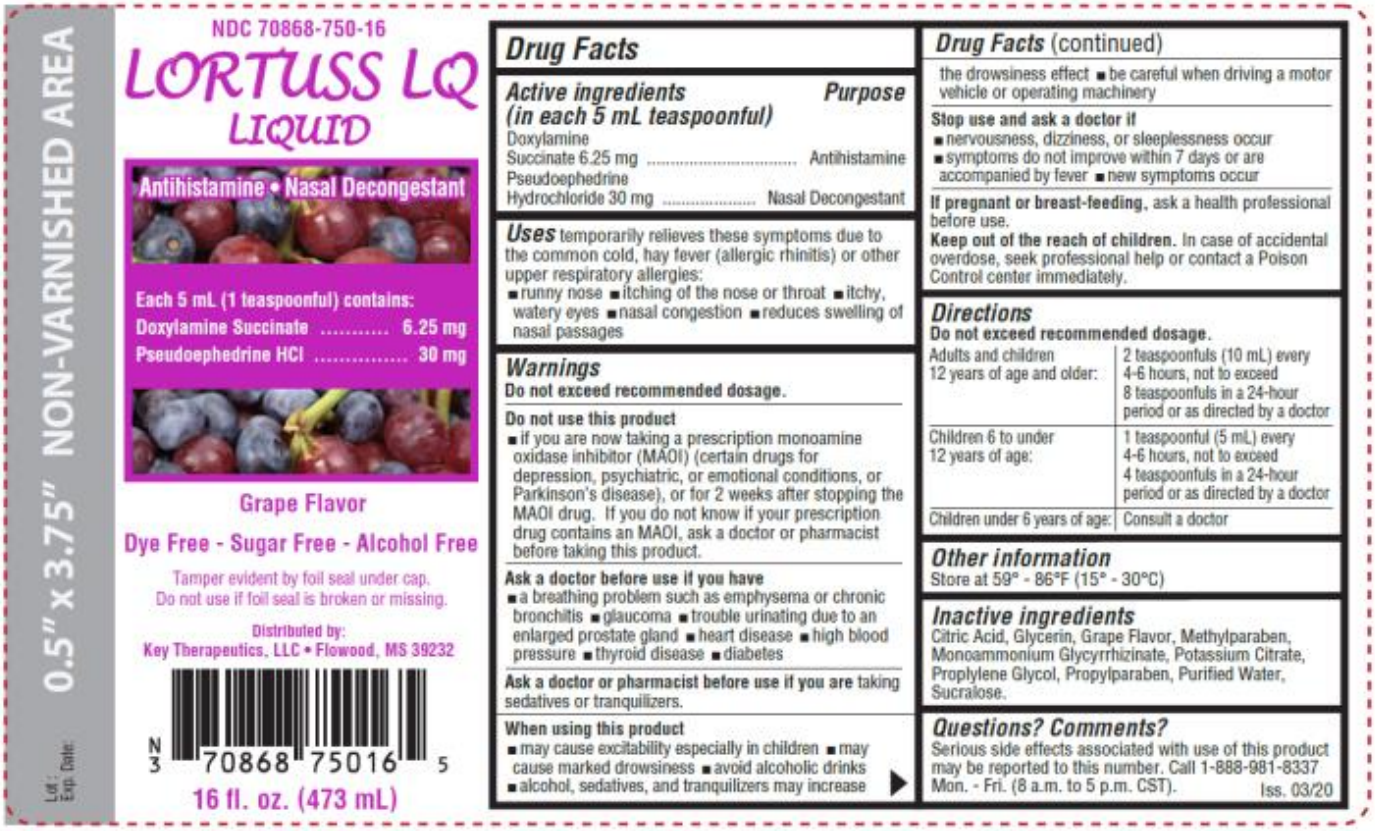
16 fl oz. (473 mL)

Distributed by:

Key Therapeutics, LLC

Flowood, MS 39232

Iss. 03/20



LORTUSS LQ

doxylamine succinate, pseudoephedrine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70868-750
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg in 5 mL
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	30 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	
POTASSIUM CITRATE (UNII: EE90ONI6FF)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

WATER (UNII: 059QF0KO0R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics			
Color		**Score**	
Shape		**Size**	
Flavor	GRAPE	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70868-750-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/15/2020	

Labeler - Key Therapeutics (080318791)

Establishment

Name	Address	ID/FEI	Business Operations
TG United		172837085	manufacture(70868-750)

Revised: 1/2022 Key Therapeutics