

ENTEX LQ - guaifenesin and phenylephrine hydrochloride liquid
Physicians Total Care, 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.

Entex LQ

Drug Facts

Active Ingredients per teaspoon (5 mL)

Guaifenesin, USP 100 mg

Phenylephrine HCl, USP 10 mg

in each 5 mL (1 teaspoonful) red, strawberry flavored liquid

Purpose

Guaifenesin, USP Expectorant

Phenylephrine HCl, USP Nasal decongestant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive
- for the temporary relief of nasal and sinus congestion due to cold, hay fever or other respiratory allergies

WARNINGS

Do not exceed recommended dosage.

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 two 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 drug.

Ask a doctor before use if you have

- a persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema or where cough is accompanied by excessive phlegm (mucus).

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur.
- symptoms do not improve within 7 days or are accompanied by fever.
- a cough persists for more than 1 week or is accompanied by a fever, rash or persistent headache.

Do not take this product if you have

- heart disease
- high blood pressure

- thyroid disease
- diabetes
- trouble urinating due to enlarged prostate gland
- breathing problems such as emphysema or chronic bronchitis.

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 immediately.

Directions

Age	Dose
Adults and children over 12 years of age	1 teaspoonful (5mL) every 4 hours;
Children 6 to under 12 years of age	1/2 teaspoonful (2.5 mL) every 4 hours;
Children 2 to under 6 years of age	1/4 teaspoon (1.25mL) every 4 hours
Children under 2 years of age	Ask your doctor

Do not exceed 6 doses in a 24 – hour period.

Other information

- store at 20°- 25°C (68°- 77°F)

Inactive ingredients

benzoic acid USP, Bitter Masking agent, citric acid USP, D&C Red #33, edetate disodium, glycerin USP, propylene glycol USP, purified water, sodium citrate dihydrate USP, sorbitol solution and strawberry flavor.

Questions or Comments?

**Call weekdays from 9 AM to 4PM CST at 1-888-252-3901 or go to <http://www.wraser.com>
email: medicalinfo@wraser.com**

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

ENTEX LQ (guaifenesin and phenylephrine hydrochloride) liquid

473 mL (5 mL per teaspoon)

NDC 54868-6241-0

DIST. BY: PHYSICIANS TOTAL CARE
TULSA, OK 74146

NDC 54868-6241-0 473 ML

ENTEX LQ LIQ - OTC

LOT # 0000 EXP. DATE 01/60

MFG. BY: SOVEREIGN PHARMACEUTICALS,
FORT WORTH TX 76118



62414730000

ENTEX LQ

guaifenesin and phenylephrine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54868-6241(NDC:66992-280)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
BENZOIC ACID (UNII: 8SKN0B0MIM)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	red	Score	
Shape		Size	
Flavor	STRAWBERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54868-6241-0	473 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	04/01/2011	

Labeler - Physicians Total Care, Inc. (194123980)**Establishment**

Name	Address	ID/FEI	Business Operations
Physicians Total Care, Inc.		194123980	relabel

Revised: 9/2010

Physicians Total Care, Inc.