ENTEX T- guaifenesin and pseudoephedrine hydrochloride tablet
WraSer Pharmaceuticals, LLC

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 Tablets

Drug Facts

Active Ingredients (in each tablet)

Guaifenesin, USP 375 mg

Pseudoephedrine HCl, USP 60 mg

Purpose

Guaifenesin, USP Expectorant

Pseudoephedrine HCl, USP Nasal decongestant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily relieves nasal congestion due to:
  - common cold
  - hay fever
  - upper respiratory allergies (allergic rhinitis)
- temporarily restores freer breathing through the nose
- promotes nasal and/or sinus drainage
- temporarily relieves sinus congestion and pressure

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 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

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough accompanied by excessive phlegm (mucus)

When using this product

do not exceed the recommended dosage

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur.
- cough or nasal congestion persists for more than 1 week, tends to recur, or is accompanied by a fever, rash or persistent headache. These could be signs of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of the reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- **Do not exceed 4 doses in a 24 hour period**
- **Adults and children 12 years of age and over:** 1 tablet every 4 hours.
- **Children 6 to under 12 years of age:** 1/2 tablet every 4 hours.

Other information

- store at 20°- 25°C (68°- 77°F)
- tamper evident: do not use if foil seal under the cap is broken or missing.
- contains 4 mg sodium in each tablet
- contains less than 1 mg magnesium in each tablet

Inactive Ingredients

croscarmellose sodium, magnesium stearate, microcrystalline cellulose, povidone, sodium starch glycolate and starch.

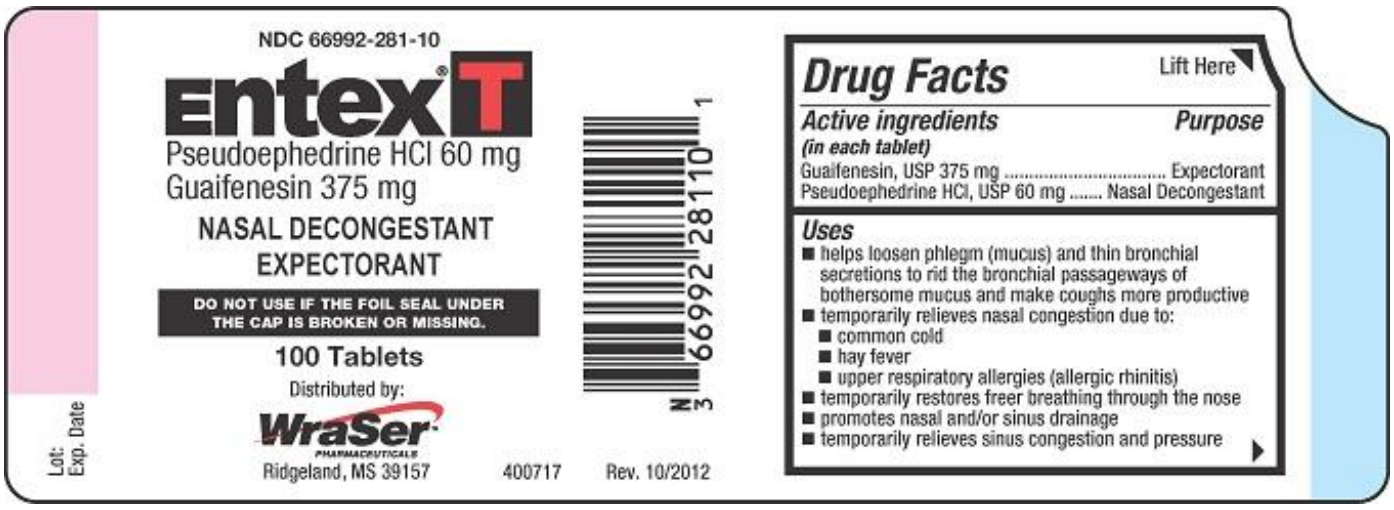
Questions or Comments

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

email:medicalinfo@wraser.com

Package Label

Figure 1: 100 ct Label Rev. 10/2012



ENTEX T

guaifenesin and pseudoephedrine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:66992-281
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	375 mg
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	60 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE K30 (UNII: U725QWY32X)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics			
Color	white	**Score**	2 pieces
Shape	OVAL	**Size**	18mm
Flavor		**Imprint Code**	375
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**

1	NDC:66992-281-10	100 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:66992-281-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	09/30/2010	12/31/2014

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	09/30/2010	

Labeler - WraSer Pharmaceuticals, LLC (121828334)

Revised: 1/2016 WraSer Pharmaceuticals, LLC