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 LABEL	**Item Code (Source)**	NDC:66992-281
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (GUAIFENESIN)	GUAIFENESIN	375 mg
PSEUDOEPHEDRINE HYDROCHLORIDE (PSEUDOEPHEDRINE)	PSEUDOEPHEDRINE HYDROCHLORIDE	60 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM	
MAGNESIUM STEARATE	
CELLULOSE, MICROCRYSTALLINE	
POVIDONE K30	
SODIUM STARCH GLYCOLATE TYPE A POTATO	
STARCH, CORN	

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		
2	NDC:66992-281-30	30 in 1 BOTTLE		

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)

Establishment

Name	Address	ID/FEI	Business Operations
Sovereign Pharmaceuticals, LLC		623168267	MANUFACTURE(66992-281)

Revised: 11/2012 WraSer Pharmaceuticals, LLC