# EXEFEN IR - guaifenes in and pseudoephedrine hydrochloride tablet Larken Laboratories, 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.

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#### **ExeFen IR Tablets**

#### **Drug Facts**

## Active Ingredients (in each tablet)

Guaifenesin, USP 400 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 (veg), microcrystalline cellulose, povidone, sodium starch glycolate and starch.

#### **Questions or Comments**

Call 1-888-527-5522 weekdays from 9 AM to 4 PM CST or go to http://www.larkenlabs.com

## **Package Label**

100 ct Label Rev. 11/2012



### **EXEFEN IR**

guaifenesin and pseudoephedrine hydrochloride tablet

#### **Product Information**

Product TypeHUMAN OTC DRUG LABELItem Code (Source)NDC:68047-157Route of AdministrationORALDEA Schedule

Active Ingredient/Active Moiety

Ingredient Name
Basis of Strength
GUAIFENESIN (GUAIFENESIN)
GUAIFENESIN
GUAIFENESIN
GUAIFENESIN
400 mg
PSEUDO EPHEDRINE HYDRO CHLO RIDE (PSEUDO EPHEDRINE)
PSEUDO EPHEDRINE HYDRO CHLO RIDE
60 mg

Inactive Ingredients	
Ingredient Name	Strength
CROSCARMELLOSE SODIUM	
MAGNESIUM STEARATE	
CELLULO SE, MICRO CRYSTALLINE	
PO VIDO NE K30	
SODIUM STARCH GLYCOLATE TYPE A POTATO	
STARCH, CORN	

Product Characteristics			
Color	WHITE	Score	2 pieces
Shape	CAPSULE	Size	18 mm
Flavor		Imprint Code	LL157
Contains			

Pacl	kaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1 NDC:68047-157-01	100 in 1 BOTTLE			
Marketing Information				
Marketing Category	Application Number or Monogra	ph Citation	Marketing Start Da	te Marketing End Date
OTC monograph final	part341		0 1/10/20 11	

## **Labeler** - Larken Laboratories, Inc. (791043719)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Sovereign Pharmaceuticals, LLC		623168267	MANUFACTURE(68047-157)	

Revised: 11/2012 Larken Laboratories, Inc.