

**GUAIFENESIN AND PSEUDOEPHEDRINE HYDROCHLORIDE EXTENDED RELEASE-**  
**guaifenesin, pseudoephedrine hydrochloride tablet, extended release**  
**Proficient Rx LP**

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**Perrigo Guaifenesin and Pseudoephedrine Hydrochloride Extended-Release Tablets Drug Facts**

**Active ingredients (in each extended-release tablet)**

Guaifenesin 600 mg

Pseudoephedrine HCl 60 mg

**Purpose**

Expectorant

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
- 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 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**

- 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 too much phlegm (mucus)

## **When using this product**

- do not use more than directed

## **Stop use and ask a doctor if**

- you get nervous, dizzy, or sleepless
- symptoms do not get better within 7 days, come back or occur with a fever, rash, or persistent headache.

These could be signs of a serious illness.

## **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 right away. (1-800-222-1222)

## **Directions**

- do not crush, chew, or break tablet
- take with a full glass of water
- this product can be administered without regard for timing of meals
- adults and children 12 years and older: 2 tablets every 12 hours; not more than 4 tablets in 24 hours
- children under 12 years of age: do not use

## **Other information**

- store between 20-25°C (68-77°F)
- do not use if blister unit is broken or torn

## **Inactive ingredients**

colloidal silicon dioxide, copovidone, FD&C yellow #6 aluminum lake, hypromellose, magnesium stearate, maltodextrin, microcrystalline cellulose, povidone, sodium starch glycolate, stearic acid

## **Questions or comments?**

1-800-719-9260

## **Package/Label Principal Display Panel**

Compare to Mucinex® D active ingredient

Guaifenesin and Pseudoephedrine Hydrochloride Extended-Release Tablets, 600 mg/60 mg

Expectorant/Nasal Decongestant

12 HOUR

Clears Nasal/Sinus Congestion

Thins and Loosens Mucus

Actual Size

18 Extended-Release Tablets

Relabeled by:

Proficient Rx LP

Thousand Oaks, CA 91320



NDC 63187-960-18

Lot #:00000  
Exp. 00/00/00  
SN# MASTER

## Guaifenesin 600mg /Pseudoephedrine HCl 60mg

### #18 ER Tablets

Each extended-release tablet contains: Guaifenesin 600 mg Expectorant / Pseudoephedrine HCl 60 mg Nasal Decongestant

Orange (peach) colored, oval, biconvex, unscored tablet with imprint code "600" and "Watson".

Product ID: RG096018

Dist. By: Perrigo Allegan, MI 49010 Made in India

Store at 20°-25°C (68°-77°F)

Keep medication out of the reach of children

Guaifenesin 600mg /Pseudoephedrine HCl 60mg  
#18 ER Tablets  
Lot #:00000 SN#MASTER  
NDC 63187-960-18 Exp:00/00/00

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Thousand Oaks, CA 91320

## GUAIFENESIN AND PSEUDOEPHEDRINE HYDROCHLORIDE EXTENDED RELEASE

guaifenesin, pseudoephedrine hydrochloride tablet, extended release

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63187-960(NDC:45802-230)
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	600 mg
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	60 mg

### Inactive Ingredients

Ingredient Name	Strength
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SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
COPOVIDONE K25-31 (UNII: D9C330MD8B)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

### Product Characteristics

Color	ORANGE (peach)	Score	no score
Shape	OVAL (biconvex)	Size	18mm
Flavor		Imprint Code	600;Watson
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63187-960-18	18 in 1 CARTON	01/01/2018	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091071	01/29/2016	

**Labeler** - Proficient Rx LP (079196022)

### Establishment

Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079196022	RELABEL(63187-960)

Revised: 11/2019

Proficient Rx LP