

GUAIFENESIN AND PSEUDOEPHEDRINE HYDROCHLORIDE- guaifenesin and pseudoephedrine hydrochloride tablet, extended release
STRATEGIC SOURCING SERVICES LLC

Guaifenesin and Pseudoephedrine Hydrochloride

Drug Facts

<i>Active ingredients (in each extended-release tablet)</i>	<i>Purposes</i>
Guaifenesin 600 mg	Expectorant
Pseudoephedrine HCl 60 mg	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 extended-release 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 extended-release tablets every 12 hours; not more than 4 extended-release tablets in 24 hours
- children under 12 years of age: do not use

Other information

- **Tamper evident: Do not use if carton is open or if printed seal on blister is broken or missing.**
- store between 20-25°C (68-77°F)

Inactive ingredients

carbomer homopolymer, NF; hypromellose, USP; magnesium stearate, NF; microcrystalline cellulose, NF

Questions?

call toll-free Monday to Friday 8:30 am to 5:00 pm EST at **1-800-406-7984**. You may also report side effects to this phone number.

**Distributed by McKesson Corp., via SSSL,
Memphis, TN 38141**

PRINCIPAL DISPLAY PANEL - 600 mg/60 mg Tablet Blister Pack Carton

NDC 62011-0475-1

Health Mart®

Compare to Mucinex®D active ingredients†

12 HOUR

Mucus Relief D

Guaifenesin 600 mg/
Pseudoephedrine HCl 60 mg
Extended-Release Tablets

Expectorant/Nasal Decongestant

Clears Nasal/Sinus Congestion
Thins And Loosens Mucus
Immediate And Extended Release

ACTUAL SIZE

18 Extended-Release Tablets



GUAIFENESIN AND PSEUDOEPHEDRINE HYDROCHLORIDE

guaifenesin and pseudoephedrine hydrochloride tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62011-0475
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
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

Product Characteristics

Color	WHITE	Score	no score
Shape	OVAL	Size	16mm
Flavor		Imprint Code	058
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62011-0475-1	1 in 1 CARTON	12/10/2017	
1		18 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	ANDA212542	11/15/2017	

Labeler - STRATEGIC SOURCING SERVICES LLC (116956644)**Establishment**

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	MANUFACTURE(62011-0475)