GUAIFENESIN AND PSEUDOEPHEDRINE HCL- guaifenesin and pseudoephedrine hcl tablet, extended release
Ohm Laboratories, Inc.

Drug Facts

Active ingredients (in each extended-release tablet)	***Purposes***
Guaifenesin 600 mg	Expectorant
Pseudoephedrine HCl 60 mg	Nasal Decongestant

Active ingredients (in each extended-release tablet)	***Purposes***
Guaifenesin 1200 mg	Expectorant
Pseudoephedrine HCl 120 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
- **For 600 mg/60 mg:** adults and children 12 years and older: 2 extended-release tablets every 12 hours; not more than 4 extended-release tablets in 24 hours
- **For 1200 mg/120 mg:** adults and children 12 years and older: 1 extended-release tablet every 12 hours; not more than 2 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.

Keep the carton. It contains important information.

See end panel for expiration date.

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Distributed by:
Ohm Laboratories Inc.
New Brunswick, NJ 08901

0321

Guaifenesin 600 mg and Pseudoephedrine HCl 60 mg Extended-Release Tablets - Carton Label

NDC 51660-074-18

† **Compare To**
the active ingredients of
Mucinex ®D

ohm ®

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

Expectorant & Nasal Decongestant

12 Hour

- *Clears Nasal/Sinus Congestion*
- *Thins and Loosens Mucus*
- *Immediate and Extended Release*

18 Extended-Release Tablets

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Guaifenesin 1200 mg and Pseudoephedrine HCl 120 mg Extended-Release Tablets - Carton Label

NDC 51660-077-12

† **Compare To**
the active ingredients of

Maximum Strength
Mucinex ®D

ohm ®

Maximum Strength
Guaifenesin 1200 mg & Pseudoephedrine HCl 120 mg
Extended-Release Tablets

Expectorant & Nasal Decongestant

12 Hour

- *Clears Nasal/Sinus Congestion*
- *Thins and Loosens Mucus*
- *Immediate and Extended Release*

12 Extended-Release Tablets

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GUAIFENESIN AND PSEUDOEPHEDRINE HCL

guaifenesin and pseudoephedrine hcl tablet, extended release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51660-074
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)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSE 2910 (10000 MPA.S) (UNII: 0HO1H52958)	

MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

Product Characteristics			
Color	white (white to off-white)	**Score**	no score
Shape	OVAL	**Size**	17mm
Flavor		**Imprint Code**	058
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51660-074-18	1 in 1 CARTON	04/01/2021	
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	04/01/2021	

GUAIFENESIN AND PSEUDOEPHEDRINE HCL

guaifenesin and pseudoephedrine hcl tablet, extended release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51660-077
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	1200 mg
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	120 mg

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
HYPROMELLOSE 2910 (10000 MPA.S) (UNII: 0HO1H52958)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

Product Characteristics			
Color	white (white to off-white)	**Score**	no score
Shape	OVAL	**Size**	22mm
Flavor		**Imprint Code**	057
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51660-077-12	1 in 1 CARTON	04/01/2021	
1		12 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	04/01/2021	

Labeler - Ohm Laboratories, Inc. (184769029)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories, Inc.		184769029	manufacture(51660-074, 51660-077)

Revised: 10/2024 Ohm Laboratories, Inc.