

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

Drug Facts

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

Active ingredients (in each extended-release bi-layer 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 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
- **For 600 mg/60 mg:** adults and children 12 years and older: 2 tablets every 12 hours; not more than 4 tablets in 24 hours
- **For 1200 mg/120 mg:** adults and children 12 years and older: 1 tablet every 12 hours; not more than 2 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; FD&C Yellow #6; hypromellose, USP; magnesium stearate, NF; microcrystalline cellulose, NF

Questions?

call **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.

†Ohm® is a registered trademark of Sun Pharmaceutical Industries, Inc. All other trademarks are property of their respective owners.

Distributed by:

Ohm Laboratories Inc.
New Brunswick, NJ 08901

0219

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

NDC 51660-058-18

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

ohm®

**Guaifenesin 600 mg & Pseudoephedrine HCl 60 mg
Extended-Release Bi-Layer Tablets**

Expectorant & Nasal Decongestant

12 Hour

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

18 Extended-Release Bi-Layer Tablets

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GLUE - NO COATING

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ohm

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18 Extended-Release Bi-Layer Tablets

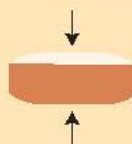
ohm

Guaifenesin 600 mg & Pseudoephedrine HCl 60 mg
Extended-Release Bi-Layer Tablets
Expectorant & Nasal Decongestant

18 Extended-Release Bi-Layer Tablets

Keep the carton. It contains important information.
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Unique Bi-Layer Tablet
Immediate-Release Layer



Extended-Release Layer
Tablet shown actual size

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(in each extended-release
bi-layer tablet)**

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Pseudoephedrine HCl 60 mg.....Nasal Decongestant

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Drug Facts (continued)

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Inactive ingredients

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Questions? call 1-800-406-7984

You may also report side effects to this phone number.

Expiration Date:

Lot No.

NON VARNISH

0219

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



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

NDC 51660-057-12

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

ohm®

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

Expectorant & Nasal Decongestant

12 Hour

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

12 Extended-Release Bi-Layer 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:51660-058

Route of Administration		ORAL		
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)		GUAIFENESIN	600 mg	
PSEUDOEPHEDRINE (UNII: 7CUC9DDI9F) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)		PSEUDOEPHEDRINE	60 mg	
Inactive Ingredients				
Ingredient Name			Strength	
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
HYPROMELLOSE 2910 (10000 MPA.S) (UNII: 0HO1H52958)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
Product Characteristics				
Color	WHITE (white to off-white) , ORANGE (orange to light orange)	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:51660-058-18	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:51660-057
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	1200 mg
PSEUDOEPHEDRINE (UNII: 7CUC9DDI9F) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE	120 mg

Inactive Ingredients	
Ingredient Name	Strength
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01Z NK31)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE 2910 (10000 MPA.S) (UNII: 0HO1H52958)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

Product Characteristics			
Color	WHITE (white to off-white) , ORANGE (orange to light orange)	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:51660-057-12	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(51660-058, 51660-057)