

GUAIFENESIN AND PSEUDOEPHEDRINE HYDROCHLORIDE- guaifenesin and pseudoephedrine hydrochloride tablet, extended release
PUBLIX SUPER MARKETS, INC

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 68-77°F (20-25°C)

Inactive ingredients

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

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PUBLIX SUPER MARKETS, INC.,
3300 PUBLIX CORPORATE PARKWAY
LAKELAND, FL 33811**

PRINCIPAL DISPLAY PANEL - 36 Tablet Blister Pack Carton

NDC 41415-994-36

12-HOUR

mucusD

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

36

EXTENDED-RELEASE
TABLETS

†Compare to the active
ingredients of Mucinex[®] D



12-HOUR

mucusD

GUAIFENESIN 600 mg & PSEUDOEPHEDRINE HCl 60 mg
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EXPECTORANT & NASAL DECONGESTANT

NDC 41415-994-36



12-HOUR

mucusD

GUAIFENESIN 600 mg &
PSEUDOEPHEDRINE HCl 60 mg
EXTENDED-RELEASE TABLETS

EXPECTORANT & NASAL
DECONGESTANT



ACTUAL SIZE

12 Hour

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

36 EXTENDED-RELEASE
TABLETS

[†]Compare to the active ingredients of Mucinex® D



12-HOUR

mucusD

GUAIFENESIN 600 mg & PSEUDOEPHEDRINE HCl 60 mg
EXTENDED-RELEASE TABLETS
EXPECTORANT & NASAL DECONGESTANT

Unique Bi-Layer Tablet

Immediate-Release Layer



Extended-Release Layer

Tablet shown actual size

Lot No.

Expiration Date:

NON VARNISH



5229860

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Keep the carton.

It contains important information. See end panel for expiration date.

[†]All trademarks are property of their respective owners. This product is not affiliated with the makers/owners of Mucinex[®] D.



SCAN HERE FOR MORE INFORMATION

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OR YOUR MONEY BACK

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GUAIFENESIN AND PSEUDOEPHEDRINE HYDROCHLORIDE

guaifenesin and pseudoephedrine hydrochloride tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41415-994
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:41415-994-18	1 in 1 CARTON	04/07/2022	
1		18 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:41415-994-36	2 in 1 CARTON	04/07/2022	
2		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	04/07/2022	

Labeler - PUBLIX SUPER MARKETS, INC (006922009)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	MANUFACTURE(41415-994)

Revised: 4/2022

PUBLIX SUPER MARKETS, INC