

GUAIFENESIN AND PSEUDOEPHEDRINE HCL - guaifenesin and pseudoephedrine hcl tablet, extended release
Aurohealth LLC

Drug Facts

Active ingredients
(in each extended-release tablet)

Guaifenesin USP 600 mg

Pseudoephedrine HCl USP 60 mg

Purposes

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

- **tamper evident:** do not use if carton is opened or if individual blister units are torn or opened.
- store at 20 to 25°C (68 to 77°F)

Inactive ingredients

colloidal silicon dioxide, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, pregelatinised starch (maize).

Questions?

1-855-274-4122 (Monday – Friday 8:30 AM to 5:00 PM EST) You may also report side effects to this phone number.

Distributed by:

AUROHEALTH LLC

2572 Brunswick Pike
Lawrenceville, NJ 08648

Made in India

Code: AP/DRUGS/04/2016

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 600 mg/60 mg (18 Tablet Carton Label)

AUROHEALTH

NDC 58602-833-12

***Compare to the active
Ingredients of Mucinex[®]D**

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

EXPECTORANT & NASAL DECONGESTANT

12 HOUR

- Clears Nasal/Sinus Congestion
- Thins And Loosens Mucus

18 Extended-Release Tablets



GUAIFENESIN AND PSEUDOEPHEDRINE HCL

guaifenesin and pseudoephedrine hcl tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58602-833
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSE 2208 (15000 MPA.S) (UNII: Z78RG6M2N2)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
MICROCRYSTALLINE CELLULOSE 101 (UNII: 7T9FYH5QMK)	
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)	
POVIDONE K25 (UNII: K0KQV10C35)	

POVIDONE K90 (UNII: RDH86HJV5Z)				
STARCH, CORN (UNII: O8232NY3SJ)				
Product Characteristics				
Color	WHITE (white to off-white)		Score	no score
Shape	OVAL (biconvex)		Size	14mm
Flavor			Imprint Code	64;X
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-833-12	1 in 1 CARTON	03/25/2020	
1		18 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:58602-833-17	2 in 1 CARTON	03/25/2020	
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		ANDA213203	03/25/2020	

Labeler - Aurohealth LLC (078728447)

Establishment			
Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650918514	ANALYSIS(58602-833) , MANUFACTURE(58602-833)

Revised: 11/2023

Aurohealth LLC