

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

Drug Facts

Active ingredients

(in each extended-release tablet)

Guaifenesin USP 1200 mg

Pseudoephedrine HCl USP 120 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 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: 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

- 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)

Distributed by:

AUROHEALTH LLC

279 Princeton-Hightstown Road
East Windsor, NJ 08520

Made in India
Code: AP/DRUGS/04/2016

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 1200 mg/120 mg (12 Tablet Carton Label)

AUROHEALTH

NDC 58602-834-77

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

MAXIMUM STRENGTH

**Guaifenesin and
Pseudoephedrine Hydrochloride
Extended-Release Tablets
1200 mg/120 mg**

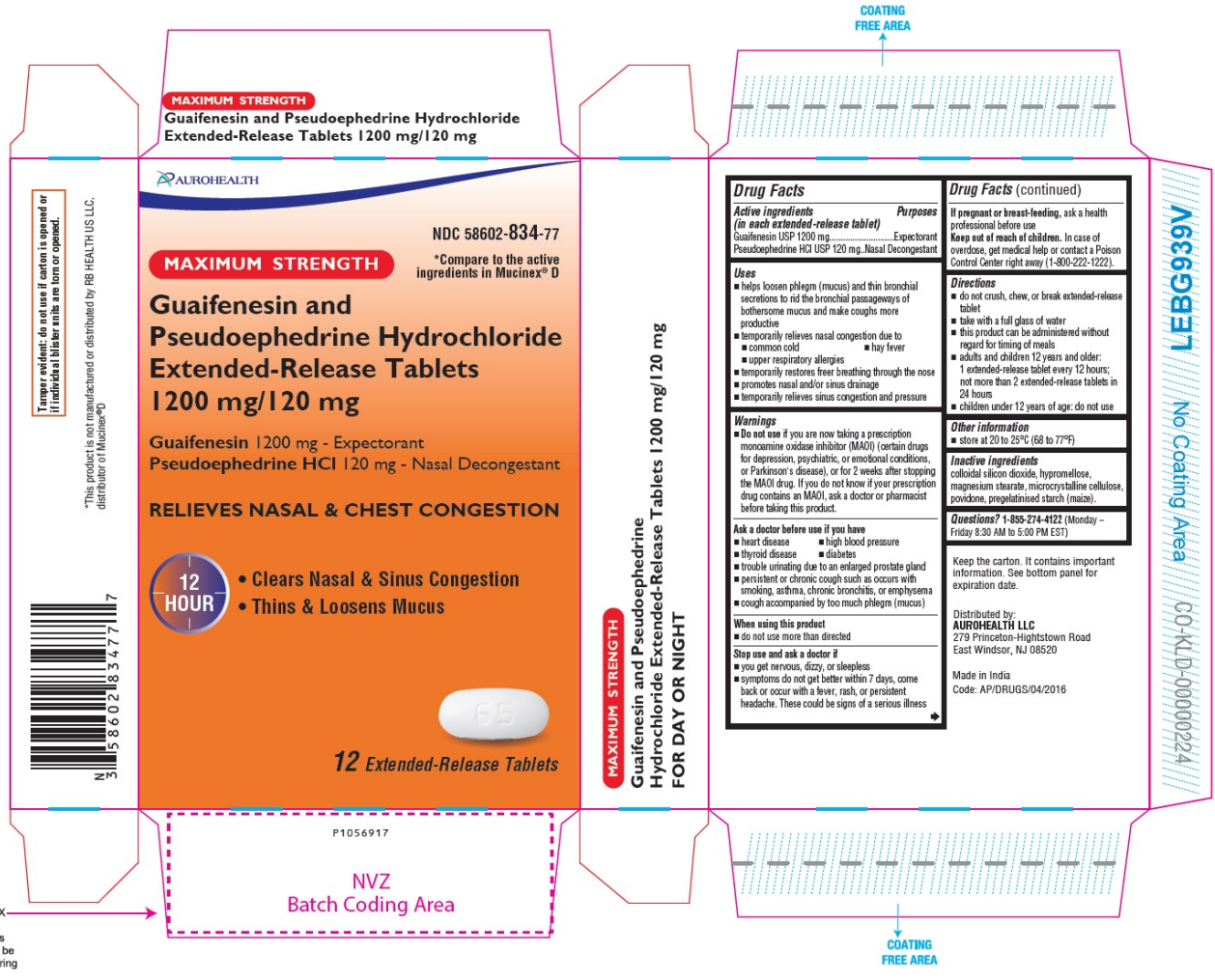
Guaifenesin 1200 mg - Expectorant
Pseudoephedrine HCl 120 mg - Nasal Decongestant

RELIEVES NASAL & CHEST CONGESTION

12 HOUR

- **Clears Nasal & Sinus Congestion**
- **Thins & Loosens Mucus**

12 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:58602-834
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSE 2208 (15000 MPA.S) (UNII: Z78RG6M2N2)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

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	CAPSULE (modified, biconvex)	Size	22mm
Flavor		Imprint Code	65;X
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-834-77	1 in 1 CARTON	03/25/2020	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:58602-834-78	2 in 1 CARTON	03/25/2020	
2		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	ANDA213203	03/25/2020	

Labeler - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650918514	ANALYSIS(58602-834) , MANUFACTURE(58602-834)

Revised: 9/2024

Aurohealth LLC