GUAIFENESIN AND PSEUDOEPHEDRINE HCL - guaifenesin and pseudoephedrine hcl tablet, extended release WALGREEN CO.

Drug Facts

Active ingredients

(in each extended-release tablet)

Guaifenesin USP 1200 mg

Pseudoephedrine HCI 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 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 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 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: WALGREEN CO.

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Made in India

Code: AP/DRUGS/04/2016

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 1200 mg/120 mg (24 Tablet Carton Label)

walgreens

Compare to the active ingredients in Mucinex® D^{††}

NDC 0363-0134-78

MAXIMUM STRENGTH

Mucus Relief D

GUAIFENESIN USP 1200 mg / EXPECTORANT PSEUDOEPHEDRINE HCI USP 120 mg / NASAL DECONGESTANT EXTENDED-RELEASE TABLETS

Maximum Strength 12 Hour

- Clears nasal/sinus congestion
- Thins & loosens mucus

24 EXTENDED-RELEASE TABLETS

ACTUAL SIZE



packaging supplier. If the packaging supplier printing the packaging does not have a code they will need to contact GMI to obtain the code and begin the required Certification process by emailing: walgreensmonitoring@sgsco.com

ORG code is an internal Periscope code, that will be updated by Periscope prior to artwork release. It is okay to move this number, but do not remove.

guaifenesin and pseudoephedrine hcl tablet, extended release

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-0134
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			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363- 0134-78	2 in 1 CARTON	08/05/2020	
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	ANDA213203	08/05/2020	

Labeler - WALGREEN CO. (008965063)

Registrant - Aurohealth LLC (078728447)

Establishment			
Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650918514	ANALYSIS(0363-0134), MANUFACTURE(0363-0134)

Revised: 4/2024 WALGREEN CO.