

**GUAIFENESIN AND PSEUDOEPHEDRINE HCL- guaifenesin and pseudoephedrine
hcl tablet, extended release
Strategic Sourcing Services, LLC**

Drug Facts

Active ingredient(s)

Guaifenesin USP, 600
mg.....Expectorant

Pseudoephedrine HCl USP, 60 mg.....Nasal
Decongestant

Guaifenesin USP, 1200
mg.....Expectorant

Pseudoephedrine HCl USP, 120 mg.....Nasal
Decongestant

Purpose

Expectorant and Nasal Decongestant

Use(s)

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of 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

- 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 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.

Pregnancy/Breastfeeding

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
- children under 12 years of age: do not use
- adults and children 12 years and older: 2 tablets every 12 hours; not more than 4 tablets in 24 hours

Other information

- tamper evident: do not use if carton is open or if printed seal on blister is broken or missing.

Storage

■ store between 20°-25°C (68°-77°F)

Inactive ingredients

FD & C yellow #6, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone, silicon dioxide.

Questions

call **1-888-375-3784**

You may also report side effect to this phone number.

Keep the carton.

It contains important information.

See end panel for expiration date.

Manufactured by:

Dr. Reddy's Laboratories Limited

Srikakulam – 532 409 INDIA

Principal Display Panel

Guaifenesin and Pseudoephedrine HCl ER Tablets 600 mg/60 mg:

Drug Facts

Active ingredients
(in each extended-release tablet)
Guaifenesin USP, 600 mg; Pseudoephedrine HCl USP, 60 mg

Purpose
Expectorant & Nasal Decongestant

Uses
help loosen phlegm (mucus) and thin bronchial secretions to aid the bronchial passageways of both the nose and throat
you get more productive coughs
temporarily relieves nasal congestion due to:
■ common cold ■ hay fever ■ upper respiratory allergies
temporarily relieves nasal and/or sinus drainage
temporarily relieves ear breathing through the nose
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 you are taking this product, ask a doctor or pharmacist before taking this product.
Ask a doctor before use if you have:
■ heart disease ■ high blood pressure ■ diabetes ■ trouble urinating due to an enlarged prostate gland ■ persistent or chronic coughs such as occurs with smoking, asthma, or chronic bronchitis, or emphysema
■ cough accompanied by too much phlegm in mucus

Other information
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).
If pregnant or breast-feeding, ask a health professional before use.
If you get nervous, dizzy, or sleepless, or 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.
When using this product:
■ do not use more than directed
■ do not use as a doctor if you get nervous, dizzy, or sleepless, or 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.
Do not crush, chew, or break tablet
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Inactive ingredients
FD & C yellow 55, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone, silicon dioxide.

Questions? call 1-888-375-3784
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Drug Facts

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DO NOT USE IF CARTON IS OPEN OR IF PRINTED SEAL ON BLISTER IS BROKEN OR MISSING

sunmark

guaifenesin 600 mg and pseudoephedrine HCl 60 mg

Extended-Release Tablets

Expectorant & Nasal Decongestant

• Clears Nasal / Sinus Congestion
• Thins and Loosens Mucus

12 HOUR

18 EXTENDED-RELEASE TABLETS

 ACTUAL SIZE

MCKESSON

Another Quality Product
Manufactured by McKesson
6555 S. Bascom Avenue, Suite 100
San Jose, CA 95128
1-800-541-5353
www.mckesson.com

MADE IN INDIA

Keep the carton. It contains important information. See end panel for expiration date.
This product is not manufactured or distributed by Pheochromocytoma, LLC.
owner of the registered trademark, Mucinex®.

LOT
EXP

REF 06/20

0 10989 95390 2

GUAIFENESIN AND PSEUDOEPHEDRINE HCL

guaifenesin and pseudoephedrine hcl tablet, extended release

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:70677-0110(NDC:55111-798)

Route of Administration	ORAL
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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
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	ORANGE	Score	no score
Shape	CAPSULE	Size	17mm
Flavor		Imprint Code	RDY;798
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70677-0110-1	1 in 1 CARTON	07/27/2020	04/30/2023
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	ANDA208369	07/27/2020	

Labeler - Strategic Sourcing Services, LLC (116956644)