

**GUAIFENESIN AND PSEUDOEPHEDRINE HCL- guaifenesin and pseudoephedrine
hcl tablet, extended release
Rite Aid Corporation**

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

guaifenesin and pseudoephedrine hcl tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-0046(NDC:55111-798)
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
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I3O)	
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:11822-0046-1	1 in 1 CARTON	02/01/2022	
1		18 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:11822-0046-2	2 in 1 CARTON	02/01/2022	
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	ANDA208369	02/01/2022	

Labeler - Rite Aid Corporation (014578892)

Establishment

Name	Address	ID/FEI	Business Operations
Dr. Reddys Laboratories Limited (SEZ UNIT)		860037244	analysis(11822-0046) , manufacture(11822-0046)

Revised: 12/2025

Rite Aid Corporation