MUCUS RELIEF D- guaifenesin and pseudoephedrine hcl tablet, extended release

Rite Aid Corporation

Drug Facts

Active ingredient(s)

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 bother some 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

For 600 mg/60 mg

■ adults and children 12 years and older: 2 tablets every 12 hours; not more than 4 tablets in 24 hours

For 1200 mg/120 mg

■ adults and children 12 years and older: 1 tablet every 12 hours; not more than 2 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- Carton

Guaifenesin and Pseudoephedrine HCl ER Tablets 1200 mg/120 mg: 24s



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Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:11822-7399(NDC:55111-799) 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)	Ps eudoephedrine Hydrochloride	120 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	22mm	
Flavor		Imprint Code	RDY;799	
Contains				

P	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:11822- 7399-4	4 in 1 CARTON	01/15/2020				
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product					
2	NDC:11822- 7399-6	2 in 1 CARTON	05/31/2020				
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	ANDA208369	01/15/2020	

Labeler - Rite Aid Corporation (014578892)

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