MUCINEX D- guaifenesin and pseudoephedrine hydrochloride tablet, extended release

A-S Medication Solutions

Mucinex® D

Drug Facts

Active ingredients (in each extended-release bi-layer tablet)

Purposes

Expectorant

Guaifenesin 600 mg Pseudoephedrine HCl 60 mg

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.

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

Other information

- tamper evident: do not use if carton is open or if printed seal on blister is broken or missing
- store at 20-25°C (68-77°F)

Inactive ingredients

carbomer homopolymer type B; FD&C yellow #6 aluminum lake; hypromellose, USP; magnesium stearate, NF; microcrystalline cellulose, NF; sodium starch glycolate, NF

Questions?

1-866-MUCINEX (1-866-682-4639) You may also report side effects to this phone number.

Dist. by: RB Health (US) Parsippany, NJ 07054-0224

Made in England

HOW SUPPLIED

Product: 50090-1075

NDC: 50090-1075-0 18 TABLET, EXTENDED RELEASE in a BLISTER PACK / 1 in a

CARTON

Guaifenesin and Pseudoephedrine Hydrochloride



MUCINEX D

guaifenesin and pseudoephedrine hydrochloride tablet, extended release

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Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50090-1075(NDC:63824-057)
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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		
carbomer homopolymer type B (allyl pentaerythritol crosslinked) (UNII: HHT01ZNK31)			
FD&C yellow NO. 6 (UNII: H77VEI93A8)			
aluminum oxide (UNII: LMI26O6933)			
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)			
magnesium stearate (UNII: 70097M6I30)			
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			

Product Characteristics				
Color	ORANGE, WHITE	Score	no score	
Shape	OVAL	Size	16mm	
Flavor		Imprint Code	Mucinex;600	
Contains				

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090- 1075-0	1 in 1 CARTON	11/28/2014	
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
NDA	NDA021585	06/26/2012	

Labeler - A-S Medication Solutions (830016429)

Establishment				
Name	Address	ID/FEI	Business Operations	
A-S Medication Solutions		830016429	RELABEL(50090-1075)	

Revised: 2/2023 A-S Medication Solutions