GUAIFENESIN D- guaifenesin and pseudoephedrine hydrochloride tablet, extended release

CARDINAL HEALTH 110, LLC. DBA LEADER

Mucus Relief D

Drug Facts

Active ingredients (in each extended-release tablet)	Purposes
Guaifenesin 600 mg	Expectorant
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 (1-800-222-1222).

Directions

- do not crush, chew, or break extended-release 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 extended-release tablets every 12 hours;
 not more than 4 extended-release 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 between 20-25°C (68-77°F)

Inactive ingredients

carbomer homopolymer, NF; hypromellose, USP; magnesium stearate, NF; microcrystalline cellulose, NF

Questions?

call toll-free Monday to Friday 8:30 am to 5:00 pm EST at **1-800-406-7984**. You may also report side effects to this phone number.

DISTRIBUTED BY CARDINAL HEALTH, DUBLIN, OHIO 43017

PRINCIPAL DISPLAY PANEL - 36 Tablet Blister Pack Carton

LEADER™

NDC 70000-0580-2

Mucus

Relief D

Guaifenesin, 600 mg

Pseudoephedrine Hydrochloride, 60 ma

Extended-Release Tablets

Expectorant | Nasal Decongestant

12-Hour

Clears Nasal/Sinus Congestion Thins and Loosens Mucus Immediate and Extended Release

Actual Size

36 EXTENDED-RELEASE TABLETS

COMPARE TO MUCINEX® D active ingredients[†]

100% Money Back Guarantee



Mucus Relief D

Guaifenesin, 600 mg Pseudoephedrine Hydrochloride, 60 mg **Extended-Release Tablets** Expectorant | Nasal Decongestant

Expectorant | Nasal Decongestant seudoephedrine Hydrochloride, 60 mg

Unique Bi-Layer Tablet mmediate-Release Layer

Extended-Release Laye

Tablet shown actual size



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100% Money Book Guarante

Lot No.

Expiration Date:

NON VARNICH



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Decongestant

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Drug Facts (continued)

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Inactive ingredients

carbomer homopolymer, NF; hypromellose, USP; magnesium stearate, NF; microcrystalline

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Keep the carton.

It contains important information. See end panel for expiration date.

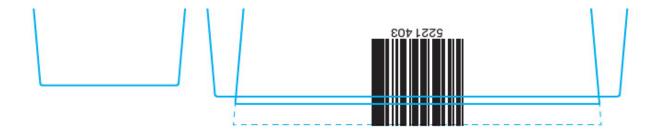
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DISTRIBUTED BY CARDINAL HEALTH, DUBLIN, OHIO 43017 www.myleader.com 1-800-200-6313

100% Money Back Guarantee

Return to place of purchase if not satisfied.





GUAIFENESIN D

guaifenesin and pseudoephedrine hydrochloride tablet, extended release

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0580
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)	Ps eudoephedrine Hydrochloride	60 mg	

Inactive Ingredients	
Ingredient Name	Strength
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

Product Characteristics			
Color	WHITE	Score	no score
Shape	OVAL	Size	16mm
Flavor		Imprint Code	058
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000- 0580-1	1 in 1 CARTON	05/06/2021	
1		18 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:70000- 0580-2	2 in 1 CARTON	05/06/2021	
		10 to 1 DUCTED DACK Town O Not a Combination		

2	18 IN 1 BLISTER PACK; Type U: NOT a Combination Product			
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA212542	05/06/2021		

Labeler - CARDINAL HEALTH 110, LLC. DBA LEADER (063997360)

Establishment				
Name	Address	ID/FEI	Business Operations	
Ohm Laboratories Inc.		184769029	MANUFACTURE(70000-0580)	

Revised: 5/2022 CARDINAL HEALTH 110, LLC. DBA LEADER