

**GUAIFENESIN D- guaifenesin and pseudoephedrine hydrochloride tablet,
extended release
RUGBY LABORATORIES, INC.**

Guaifenesin D

Drug Facts

<i>Active ingredients (in each extended-release tablet)</i>	<i>Purposes</i>
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 **1-800-645-2158**. You may also report side effects to this phone number.

Distributed by:

RUGBY® LABORATORIES

Livonia, MI 48152

PRINCIPAL DISPLAY PANEL - 36 Tablet Blister Pack Carton

Rugby®

NDC 0536-1333-36

Compare to the active ingredients in Mucinex[®] D†

Guaifenesin and
Pseudoephedrine HCl
Extended-Release Tablets
Guaifenesin 600 mg
Pseudoephedrine HCl 60 mg

600 mg/60 mg

Expectorant and Nasal Decongestant

12 Hour

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

Actual Size

36 Extended-Release Tablets



Guaifenesin and Pseudoephedrine HCl Extended-Release Tablets

Guaifenesin 600 mg
Pseudoephedrine HCl 60 mg

NDC 0536-1333-36

Compare to the active
ingredients in Mucinex® D†



Guaifenesin and Pseudoephedrine HCl Extended-Release Tablets

Guaifenesin 600 mg
Pseudoephedrine HCl 60 mg

600 mg/60 mg

Expectorant and Nasal Decongestant

12 Hour

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

Actual Size



36 Extended-Release Tablets



**Guaifenesin and Pseudoephedrine HCl
Extended-Release Tablets**
Guaifenesin 600 mg
Pseudoephedrine HCl 60 mg

Unique Bi-Layer Tablet
Immediate-Release Layer



Extended-Release Layer
Tablet shown actual size

Lot No.

Expiration Date:

NON VARNISH



5220268

**Guaifenesin and Pseudoephedrine HCl
Extended-Release Tablets**



**Guaifenesin 600 mg
Pseudoephedrine HCl 60 mg**

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:
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 - hay fever
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- temporarily restores freer breathing through the nose
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Ask a doctor before use if you have

- heart disease
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- 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.

Drug Facts (continued)

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

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Questions? call toll-free Monday to Friday 8:30 am to 5:00 pm EST at 1-800-645-2158. You may also report side effects to this phone number.

Keep the carton.
It contains important information. See end panel for expiration date.

†All trademarks are property of their respective owners. This product is not affiliated with the makers/owners of Mucinex® D.

Distributed by:
RUGBY® LABORATORIES
Livonia, MI 48152
www.rugbylaboratories.com

Rev. 06/21 R-59 Re-order No. 371091



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5220268

GLUE - NO COATING

GUAIFENESIN D

guaifenesin and pseudoephedrine hydrochloride tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1333
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: HHT01Z NK31)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I3O)	
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:0536-1333-36	2 in 1 CARTON	04/04/2022	
1		18 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0536-1333-21	1 in 1 CARTON	04/04/2022	
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	ANDA212542	04/04/2022	

Labeler - RUGBY LABORATORIES, INC. (079246066)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	MANUFACTURE(0536-1333)

Revised: 5/2022

RUGBY LABORATORIES, INC.