# MUCUS RELIEF EXTENDED RELEASE- guaifenesin tablet Redpharm Drug Inc.

-----

### **Drug Facts**

### Active ingredient (in each extended-release tablet)

Guaifenesin 600 mg

## **Purpose**

Expectorant

#### Uses

Helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and makes coughs more productive.

#### Warnings

#### Do not use

for children under 12 years of age.

## Ask a doctor before use if you have

- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema
- cough accopanied by too much phlegm (mucus)

## Stop use and ask a doctor if

cough lasts more than 7 days, comes back, or occurs with 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 tablet
- take with a full glass of water
- this product can be administered without regard for the timing of meals

- adults and children 12 years of age and over: 1 or 2 tablet every 12 hours. Do not exceed 4 tablets in 24 hours.
- children under 12 years of age: do not use

#### Other information

• store between 20° to 25°C (68° to 77°F)

#### Inactive ingredients

carbomer, colloidal silicon dioxide, FD&C blue #1 aluminum lake, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone, talc

#### **Questions or comments?**

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

### **Principal Display Panel**

Compare to the active ingredient in Mucinex®\*

Mucus Relief

Guaifenesin 600 mg

Expectorant

12-hour relief

Relieves chest congestion

Thins and loosens mucus

Extended-release tablets

\*This product is not manufactured or distributed by Reckitt Benckiser LLC, distributor of Mucinex®.

# TAMPER EVIDENT: DO NOT USE IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.

# KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Distributed by:

### **Rugby Laboratories**

17177 N Laurel Park Drive, Suite 233

Livonia. MI 48152

www.rugbylaboratories.com

## Package Label

#### Drug Facts Active ingredient Purpose (in each extended-release tablet) Guaifenesin 600 mg... Expectoran **Uses** Helps loosen phiegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive. Warnings Do not use for children under 12 years of age. Ask a doctor before use if you have ■ persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysem ■ cough accompanied by too much phlegm (mucus) Stop use and ask a doctor if cough lasts more than 7 days, comes back, or occurs with 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 tablet take with a full glass of water take with a full glass of water this product can be administered without regard for the timing of meals adults and children 12 years of age and over: 1 or 2 tablets every 12 hours. Do not exceed 4 tablets in 24 hours. children under 12 years of age: do not use Other information store between 20° to 25°C (68° to 77°F) Inactive ingredients carbomer, colloidal silicon dioxide, FD&C blue #1 aluminum lake, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone, talc Questions or comments? Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

\*This product is not manufactured or distributed by Reckitt Benckiser LLC, distributor of Mucinex®.

Re-order No. 370666 R-58 Rev. 08/18

Distributed by: **Rugby Laboratories** 17177 N Laurel Park Drive, Suite 233 Livonia, MI 48152 www.rugbylaboratories.com









NDC 0536-1163-61

Compare to the active ingredient in Mucinex\*\*

# **Mucus Relief**

Guaifenesin 600 mg Expectorant

12-hour relief
Relieves chest congestion
Thins and loosens mucus



100 Extended-release tablets

TAMPER EVIDENT: DO NOT USE IF BLISTER UNIT IS
TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Lot No.: Exp. Date:

# **MUCUS RELIEF EXTENDED RELEASE**

guaifenesin tablet

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:67296-1467(NDC:0536-1163)

Route of Administration ORAL

## **Active Ingredient/Active Moiety**

I	Ingredient Name	Basis of Strength	Strength
I	GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	600 mg

Inactive Ingredients	
Ingredient Name	Strength

CARBOMER 934 (UNII: Z135WT9208)	
· · · · · · · · · · · · · · · · · · ·	
SILICON DIOXIDE (UNII: ETJ7Z 6XBU4)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ 989GH94E)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics				
Color	blue	Score	no score	
Shape	OVAL	Size	16mm	
Flavor		Imprint Code	AN036	
Contains				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:67296- 1467-7	1 in 1 BOTTLE; Type 0: Not a Combination Product	08/31/2018	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207342	08/31/2018	

# Labeler - Redpharm Drug Inc. (828374897)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Redpharm Drug Inc.		828374897	repack(67296-1467)	

Revised: 2/2023 Redpharm Drug Inc.