# GUAIFENESIN AND DEXTROMETHORPHAN HYDROBROMIDE- guaifenes in and dextromethorphan hydrobromide tablet, extended release Rite-Aid

-----

# Guaifenes in and Dextromethorphan Hydrobromide

# **Drug Facts**

Active ingredients (in each extended-release tablet)	Purposes
Dextromethorphan HBr 60 mg	Cough suppressant
Guaifenesin 1200 mg	Expectorant

# Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily relieves:
  - cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
  - the intensity of coughing
  - the impulse to cough to help you get to sleep

# **Warnings**

#### Do not use

- for children under 12 years of age
- 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

- 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

• 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 timing of meals
- adults and children 12 years and older: 1 tablet every 12 hours; not more than 2 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 type B; hypromellose, USP; magnesium stearate, NF; microcrystalline cellulose, NF; sodium starch glycolate, NF

## Questions?

(1-800-406-7984)

You may also report side effects to this phone number.

DISTRIBUTED BY: WALGREEN CO. 200 WILMOT RD., DEERFIELD, IL 60015

## PRINCIPAL DISPLAY PANEL - 14 Tablet Blister Pack Carton

RITE AID

**PHARMACY** 

<sup>†</sup>Compare to the active ingredients of Maximum Strength Mucinex<sup>®</sup> DM

**MAXIMUM STRENGTH** 

mucus relief DM

guaifenesin 1200 mg & dextromethorphan HBr 60 mg extended-release tablets

expectorant & cough suppressant

12 HOUR controls cough thins and loosens mucus immediate and extended release

ACTUAL SIZE

14 EXTENDED-RELEASE TABLETS



14 EXTENDED-RELEASE TABLETS

MAXIMUMSTRENGTH

# mucus relief DM

guaifenesin 1200 mg & dextromethorphan HBr 60 mg extended-release tablets

expectorant & cough suppressant



14 EXTENDED-RELEASE TABLETS



expectorant & cough suppressant



†Compare to the active ingredients of Maximum Strength Mucinex® DM

# **MAXIMUM STRENGTH**

# mucus relief DM

guaifenesin 1200 mg & dextromethorphan HBr 60 mg extended-release tablets

expectorant & cough suppressant

# 12 HOUR

controls cough
thins and loosens mucus
immediate and extended release



ACTUAL SIZE

**14** EXTENDED-RELEASE TABLETS







50844 ORG051053311
DISTRIBUTED BY: RITE AID
30 HUNTER LANE
CAMP HILL, PA 17011

Lot No.

**Expiration Date:** 

**NON VARNISH** 





5188214

Purposes

# Drug Facts

## Active ingredients (in each extendedrelease tablet)

Dextromethorphan HBr 60 mg......Cough suppressant

Guaifenesin 1200 mg......Expectorant

#### Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily relieves:
  - cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
  - the intensity of coughing
  - the impulse to cough to help you get to sleep

#### Warnings Do not use

- for children under 12 years of age
- 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

- 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

 cough lasts more than 7 days, comes back, or occurs with 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

- 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: 1 tablet every 12 hours; not more than 2 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 type B; hypromellose, USP; magnesium stearate, NF; microcrystalline cellulose, NF; sodium starch glycolate, NF

#### Questions? (1-800-406-7984)

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. MUCINEX is a registered trademark of RB HEALTH (US) LLC.



www.StopMedicineAbuse.org

R0519

# GLUE - NO COATING



RITE AID PHARMACY

 $^{\dagger}\text{Compare}$  to the active ingredients of Maximum Strength Mucinex  $^{\circledR}$  DM

# MAXIMUM STRENGTH

mucus relief DM

guaifenesin 1200 mg & dextromethorphan HBr 60 mg extended-release tablets

expectorant & cough suppressant

12 HOUR controls cough thins and loosens mucus immediate and extended release

ACTUAL SIZE

28 EXTENDED-RELEASE TABLETS



# MAXIMUM STRENGTH

# mucus relief DM

28 EXTENDED-RELEASE TABLETS

& dextromethorphan HBr 60 mg extended-release tablets

expectorant & cough suppressant



†Compare to the active ingredients of Maximum Strength Mucinex® DM



# mucus relief DM

quaifenesin 1200 mg & dextromethorphan HBr 60 mg extended-release tablets

> expectorant & cough suppressant



controls cough thins and loosens mucus immediate and extended release



**ACTUAL** SIZE

28 EXTENDED-RELEASE TABLETS

50844 ORG051053311

†All trademarks are property of their respective owners. MUCINEX is a registered trademark of RB HEALTH (US) LLC.

**Expiration Date:** 





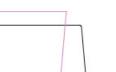












# Drug Facts

#### Active ingredients (in each extendedrelease tablet)

Drug Facts (continued) If pregnant or breast-feeding, ask a health Purposes professional before use

Dextromethorphan HBr 60 mg......Cough suppressant Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away

# Guaifenesin 1200 mg......Expectorant

#### Directions

(1-800-222-1222).

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- do not crush, chew, or break tablet take with a full glass of water
- temporarily relieves:
- this product can be administered without regard for timing of meals

1/2

ı

NO COATING

- cough due to minor throat and bronchial irritation as may occur with the common
- adults and children 12 years and older: 1 tablet every 12 hours; not more than 2 tablets in 24 hours
- cold or inhaled irritants
- children under 12 years of age: do not use

 the intensity of coughing ■ the impulse to cough to help you get to

#### 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)

#### Warnings Do not use

#### Inactive ingredients

■ for children under 12 years of age

carbomer homopolymer type B; hypromellose, USP; magnesium stearate, NF; microcrystalline cellulose, NF; sodium starch glycolate, NF

■ 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.

#### Questions? (1-800-406-7984)

You may also report side effects to this phone number.

#### Ask a doctor before use if you have

Keep the carton.

 persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema

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

cough accompanied by too much phlegm



When using this product

do not use more than directed

#### 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.

# GUAIFENESIN AND DEXTROMETHORPHAN HYDROBROMIDE

guaifenesin and dextromethorphan hydrobromide tablet, extended release

## **Product Information**

	Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-7156
Route of Administration ORAL		ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	1200 mg	
<b>DEXTROMETHO RPHAN HYDRO BRO MIDE</b> (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	60 mg	

Inactive Ingredients	
Ingredient Name	Strength
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics				
Color	WHITE	Score	no score	
Shape	OVAL	Size	22mm	
Flavor		Imprint Code	xeunciM;1200	
Contains				

P	Packaging					
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>		
1	NDC:11822-7156-9	1 in 1 CARTON	09/05/2017			
1		14 in 1 BLISTER PACK; Type 0: Not a Combination Product				
2	NDC:11822-7156-0	1 in 1 CARTON	09/07/2017			
2		28 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	NDA021620	09/05/2017		

# **GUAIFENESIN AND DEXTROMETHORPHAN HYDROBROMIDE**

guaifenesin and dextromethorphan hydrobromide tablet, extended release

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-8157	
Route of Administration	ORAL			

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	1200 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	60 mg

Inactive Ingredients	
Ingredient Name	Strength
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics			
Color	WHITE	Score	no score
Shape	OVAL	Size	22mm
Flavor		Imprint Code	xeunciM;1200
Contains			

Packaging				
# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date	
1 NDC:11822-8157-0	1 in 1 CARTON	09/05/2017	09/06/2017	
1	28 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	NDA021620	09/05/2017	09/06/2017		

# **Labeler -** Rite-Aid (014578892)

Establishment					
Name	Address	ID/FEI	Business Operations		
RECKITT BENCKISER HEALTHCARE INTERNATIONAL LTD		230780363	MANUFACTURE(11822-7156, 11822-8157), PACK(11822-7156, 11822-8157), LABEL(11822-7156, 11822-8157)		

Revised: 6/2019 Rite-Aid