GUAIFENESIN EXTENDED-RELEASE 600 MG - guaifenesin tablet, extended release
GUAIFENESIN EXTENDED-RELEASE 1200 MG - guaifenesin tablet, extended release
Guardian Drug Company

Guaifenesin Extended Release Tablets 600 mg and 1200 mg

ACTIVE INGREDIENT(in each extended-release tablet)

Guaifenesin 600 mg

PURPOSE

Expectorant

USE(S)

helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

WARNING

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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 accompanied by too much phlegm (mucus)

STOP USE AND A ASK 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 tablets every 12 hours.
- Do not exceed 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 between 20 to 25°C (68 to 77°F)

INACTIVE INGREDIENTS

carbomer homopolymer, hypromellose, microcrystalline cellulose, povidone

QUESTIONS?

1-609-860-2600
Hours: 8am - 4pm, EST
You may also report side effects to this phone number.

ACTIVE INGREDIENT (in each extended-release tablet)

Guaifenesin 1200 mg

PURPOSE

Expectorant

USE(S)

helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

WARNINGS

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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 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
- this product can be administered without regard for the timing of meals
- adults and children 12 years of age and over: 1 tablet every 12 hours.
- Do not exceed 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 to 25°C (68 to 77°F)

INACTIVE INGREDIENTS

carbomer homopolymer, hypromellose, microcrystalline cellulose, povidone

QUESTIONS?

1-609-860-2600

Hours: 8am - 4pm, EST

You may also report side effects to this phone number.

PRINCIPAL DISPLAY PANEL 600 MG

NDC 53041-233-32

GUARDIAN

12 HOUR

Guaifenesin

Extended-Release

Tablets 600 mg

Expectorant

Relieves Chest Congestion

Thins and Loosens Mucus

20 EXTENDED-RELEASE TABLETS

PRINCIPAL DISPLAY PANEL 1200 MG

NDC 53041-234-58

GUARDIAN

12 HOUR

MAXIMUM STRENGTH

Guaifenesin

Extended-Release

Tablets 1200 mg

Expectorant

Relieves Chest Congestion

Thins and Loosens Mucuc

14 EXTENDED-RELEASE TABLETS

GUAIFENESIN EXTENDED-RELEASE 600 MG

guaifenesin tablet, extended release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:53041-233
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	600 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
HYPROMELLOSE 2208 (100000 MPA.S) (UNII: VM7F0B23ZI)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	

Product Characteristics			
Color	WHITE	**Score**	no score
Shape	CAPSULE	**Size**	17mm
Flavor		**Imprint Code**	G233
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:53041-233-32	2 in 1 CARTON	03/01/2018	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:53041-233-30	1 in 1 CARTON	03/01/2018	
2		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:53041-233-38	4 in 1 CARTON	03/01/2018	
3		10 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	ANDA209215	03/01/2018	

GUAIFENESIN EXTENDED-RELEASE 1200 MG

guaifenesin tablet, extended release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:53041-234
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	1200 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
HYPROMELLOSE 2208 (100000 MPA.S) (UNII: VM7F0B23ZI)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	

Product Characteristics			
Color	WHITE	**Score**	no score
Shape	CAPSULE	**Size**	22mm

Flavor		**Imprint Code**	G234
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53041-234-58	2 in 1 CARTON	03/01/2018	
1		7 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:53041-234-37	4 in 1 CARTON	03/01/2018	
2		7 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:53041-234-47	6 in 1 CARTON	03/01/2018	
3		7 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	ANDA209215	03/01/2018	

Labeler - Guardian Drug Company (119210276)

Establishment

Name	Address	ID/FEI	Business Operations
Guardian Drug Company		119210276	MANUFACTURE(53041-233, 53041-234)

Revised: 2/2018 Guardian Drug Company