

CRCLE GUAIFENESIN EXTENDED-RELEASE TABLETS, 600 MG- guaifenesin extended-release tablet
CRCLE GUAIFENSIN EXTENDED RELEASE TABLET, 1200 MG- guaifensin extended-release tablet
Innovus Pharmaceuticals, Inc.

Guaifenesin Extended-Release Tablets

Active ingredient

Guaifenesin 600 mg (for 600 mg)
Guaifenesin 1200 mg (for 1200 mg)

Purpose

Expectorant

Uses

- helps loosen phlegm (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 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 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. (For 600mg)
- adults and children 12 years of age and over: 1 tablet every 12 hours. Do not exceed 2 tablets in 24 hours.(For 1200mg)
- 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, Lake of FD&C Blue 1, magnesium stearate, microcrystalline cellulose; sodium starch glycolate

Questions?

Contact **1-877-770-3183** Mon-Fri 8:00 AM EST to 5:00 PM PST.

Circle Guaifenesin Extended-Release Tablets

600 mg / Expectorant


100 (20x5) Extended-Release Bi-Layer Tablets

NDC 57485-200-02




Guaifenesin

Extended-Release Tablets 600 mg / Expectorant



- Relieves chest congestion
- Thins and loosens mucus
- Immediate and extended release

*Compare to the active ingredient of Mucinax®



Actual Size

100 (20x5) EXTENDED-RELEASE BI-LAYER TABLETS

Keep the carton. It contains important information.
Temporarily absent. Do not use if carton is open or if printed seal on blister is broken or missing.

Drug Facts	
Active Ingredient (in each extended-release bi-layer tablet)	Purpose
Guaifenesin 600 mg	Expectorant
Uses	
• helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of thickened 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 emphysema	
• cough accompanied by red, swollen 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 if 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 (1-800-332-1232).	
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 of age and over: 1 tablet every 12 hours. Do not exceed 4 tablets in 24 hours	
• children under 12 years of age: do not use	
Other information	
• Temporarily absent: 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	
carbonate hemophosphate type II, hydroxyethylcellulose, magnesium stearate, microcrystalline cellulose, sodium starch glycolate	
Questions?	
Contact 1-877-770-3183 Mon-Fri 8:00 AM EST to 5:00 PM PST.	

*All trademarks are property of their respective owners. MUCINAX is the registered trademark of Rckitt Bone New LLC.

Distributed by:
Innovative Pharmaceutical, Inc.
Englewood, CO 80112
www.crdabhealth.com

MADE IN INDIA




10040 10.22

57483 00249


C'rcle Guaifenesin Extended-Release Tablets
1200 mg / Expectorant
56 (14x4) Extended-Release Bi-Layer Tablets

NDC 57485-270-01




Guaifenesin

Maximum Strength Extended-Release Tablets 1200 mg / Expectorant



- Relieves chest congestion
- Thins and loosens mucus
- Immediate and extended release

*Compare to the active ingredient of Mucinax®



Actual Size

56 (14x4) EXTENDED-RELEASE BI-LAYER TABLETS


Keep the carton. It contains important information.
Temporarily absent. Do not use if carton is open or if printed seal on blister is broken or missing.

Drug Facts	
Active Ingredient (in each extended-release bi-layer tablet)	Purpose
Guaifenesin 1200 mg	Expectorant
Uses	
• helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of thickened 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 emphysema	
• cough accompanied by red, swollen 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 if 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 (1-800-332-1232).	
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 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	
• Temporarily absent: 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	
carbonate hemophosphate type II, hydroxyethylcellulose, magnesium stearate, microcrystalline cellulose, sodium starch glycolate	
Questions?	
Contact 1-877-770-3183 Mon-Fri 8:00 AM EST to 5:00 PM PST.	

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www.crdabhealth.com

MADE IN INDIA



10042 10.22

57483 00250

CRCLE GUAIFENESIN EXTENDED-RELEASE TABLETS, 600 MG
guaifenesin extended-release tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57483-270
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, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	blue (white and blue)	Score	no score
Shape	OVAL	Size	16mm
Flavor		Imprint Code	G;600
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57483-270-01	5 in 1 CARTON	04/28/2023	
1		20 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	ANDA213420	09/10/2020	

CRCLE GUAIFENSIN EXTENDED RELEASE TABLET, 1200 MG

guaifensin extended-release tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57483-280
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, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYPRMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	blue (white-blue)	Score	no score
Shape	OVAL (ellipitcal)	Size	22mm
Flavor		Imprint Code	G;1200
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57483-280-02	4 in 1 CARTON	04/28/2023	
1		14 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	ANDA213420	09/10/2020	

Labeler - Innovus Pharmaceuticals, Inc. (962507187)

Revised: 4/2023

Innovus Pharmaceuticals, Inc.