

365 WHOLE FOODS MARKET GUAIFENESIN - guaifenesin tablet, extended release

Whole Foods Market, Inc.

Drug Facts

Active ingredient

(in each extended-release tablet)

Guaifenesin USP 600 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 extended-release 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 extended-release tablets every 12 hours. Do not exceed 4 extended-release 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

colloidal silicon dioxide, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, and pregelatinised starch (maize)

Questions?

1-855-274-4122 (Monday – Friday 8:30 AM to 5:00 PM EST)

DISTRIBUTED BY:

WHOLE FOODS MARKET
550 BOWIE STREET, AUSTIN, TX 78703
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www.wholefoodsmarket.com

PRODUCT OF INDIA

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 600 mg (20 Tablets Container Label)

**365
WHOLE FOODS
MARKET**

NDC 42681-0057-1

Expectorant

Mucus Relief

**Guaifenesin
Extended-Release Tablets 600mg**

**Guaifenesin 600mg- Expectorant
Relieves Chest Congestion
Thins & Loosens Mucus**

12 20
Hour Extended-Release
TABLETS

NDC 42681-0057-1

365
WHOLE FOODS
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Expectorant

Mucus Relief

Guaifenesin
Extended-Release Tablets 600mg
Guaifenesin 600mg - Expectorant

Relieves Chest Congestion
Thins & Loosens Mucus

12
Hour

20
Extended-Release
TABLETS

Tamper Evident: Do not use if the printed seal under cap is open or torn

Drug Facts	Active ingredient (in each extended-release tablet)	Purpose
Guaifenesin USP 600 mg.	Guaifenesin 600 mg.	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 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 of age and over: ■ or 2 extended-release tablets every 12 hours. Do not exceed 4 extended-release 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 colloidal silicon dioxide, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, and pregelatinised starch (maize)	
Questions?	1-855-274-4122 (Monday – Friday 8:30 AM to 5:00 PM EST)	
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PRODUCT OF INDIA	P 14 37782	

Unvarnished Zone
(dotted line not for printing)
40 x 12 mm

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 600 mg (20 Tablets Container Carton)

365
WHOLE FOODS
MARKET

NDC 42681-0057-1

Expectorant

Mucus Relief

Guaifenesin
Extended-Release Tablets 600mg
Guaifenesin 600mg - Expectorant

Compare to the Active Ingredient in Mucinex®**

**Relieves Chest Congestion
Thins & Loosens Mucus**

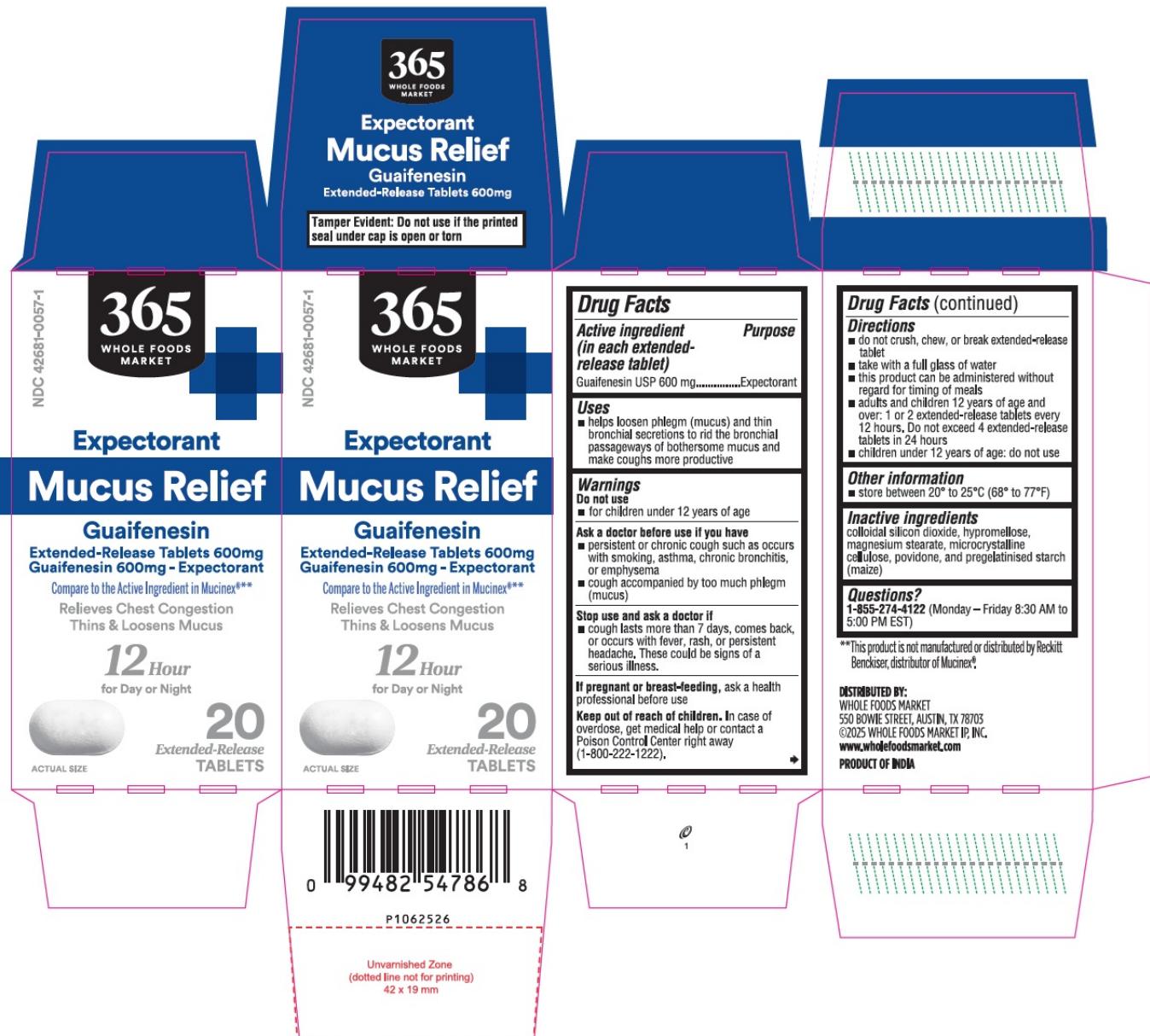
12 Hour

for Day or Night

ACTUAL SIZE

20

Extended-Release
TABLETS



365 WHOLE FOODS MARKET GUAIFENESIN
guaifenesin tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDG:42681-0057
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSE 2208 (15000 MPA.S) (UNII: Z78RG6M2N2)	
HYPROMELLOSE 2910 (10000 MPA.S) (UNII: 0HO1H52958)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE 101 (UNII: 7T9FYH5QMK)	
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)	
POVIDONE K90 (UNII: RDH86HJV5Z)	
POVIDONE K25 (UNII: K0KQV10C35)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	WHITE (white to off-white)	Score	no score
Shape	oval	Size	16mm
Flavor		Imprint Code	L;68
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42681-0057-1	1 in 1 CARTON	01/23/2026	
1		20 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210453	01/23/2026	

Labeler - Whole Foods Market, Inc. (196175616)

Registrant - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650918514	ANALYSIS(42681-0057) , MANUFACTURE(42681-0057)

