

GUAIFENESIN- guaifenesin tablet, extended release
Publix Super Markets, Inc

GUAIFENESIN EXTENDED-RELEASE TABLETS, 600 mg

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: one or two 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 68-77°F (20-25°C)
- **TAMPER EVIDENT: DO NOT USE IF CARTON IS OPEN OR IF PRINTED SEAL ON BLISTER IS BROKEN OR MISSING.**

Inactive ingredients

colloidal silicon dioxide, FD&C blue #2 aluminum lake, hypromellose, magnesium stearate, povidone.

**DISTRIBUTED BY PUBLIX SUPER MARKETS, INC.,
3300 PUBLIX CORPORATE PARKWAY
LAKELAND, FL 33811**

PRINCIPAL DISPLAY PANEL - 20 extended-release Tablets Blister Pack Carton

NDC 41415-996-20

12-HOUR
mucus relief

GUAIFENESIN EXTENDED-RELEASE
TABLETS, 600 mg

EXPECTORANT

12 Hour

- Relieves Chest Congestion
- Thins and Loosens Mucus

20
EXTENDED-RELEASE
TABLETS

†Compare to the active
ingredient of Mucinex®



GUAIFENESIN

guaifenesin tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41415-996
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
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

FD&C BLUE NO. 2 (UNII: L06K8R7DQK)

POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)

Product Characteristics

Color	WHITE	Score	no score
Shape	OVAL	Size	16mm
Flavor		Imprint Code	RH98
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41415-996-20	1 in 1 CARTON	02/08/2018	
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	ANDA209254	01/08/2018	

Labeler - Publix Super Markets, Inc (006922009)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	MANUFACTURE(41415-996)

Revised: 2/2022

Publix Super Markets, Inc