

GUAIFENESIN EXTENDED-RELEASE- guaifenesin tablet, multilayer, extended release

Precision Dose Inc.

Guaifenesin Extended-Release

Drug Facts

Active ingredient (in each extended-release tablet)

Guaifenesin 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

- Use as directed per healthcare professional.
- 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.

- children under 12 years of age: do not use

Other information

- store at 20-25°C (68-77°F)

Inactive ingredients

Carbomer homopolymer type B, FD&C blue #1 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, sodium starch glycolate

Questions or comments?

1-800-397-9228

Gluten Free

How Supplied

NDC 68094-048-61

Unit Dose Packages of 100 Tablets (10×10) per Carton

Distributed by:

Perrigo

Allegan, MI 49010

Packaged by:

Precision Dose, Inc.

South Beloit, IL 61080

For inquiries call Precision Dose, Inc. at 1-800-397-9228 or email druginfo@precisiondose.com

LI1382 Rev. 06/22

PRINCIPAL DISPLAY PANEL - 600 mg Tablet Blister Pack Carton

PrecisionDose™

NDC 68094-048-61

Unit Dose

guaifENesin
Extended-Release
Tablets,

600 mg

100 Tablets
(10 x 10)

(in each extended-release tablet)
Guaifenesin 600 mg....Expectorant.

Directions: do not crush, chew, or
break tablet take with a full glass of water

Unique Bi-Layer Tablet
GLUTEN FREE

USUAL DOSE: See Enclosed Drug Facts
Store at 20-25°C (68-77°F)

Keep out of reach of children.
Hospital Use Only.

LC1384
R0

Packaged by:
Precision Dose, Inc.
South Beloit, IL 61080



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NDC 68094-048-61

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LI1382 Rev. 06/22

GUAIFENESIN EXTENDED-RELEASE

guaifenesin tablet, multilayer, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68094-048(NDC:0113-2023)
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 OR ALLYL SUCROSE CROSSLINKED) (UNII: K6MOM3T5YL)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I3O)	

MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)

Product Characteristics

Color	BLUE	Score	no score
Shape	OVAL	Size	16mm
Flavor		Imprint Code	L2X2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68094-048-61	10 in 1 CARTON	03/22/2023	
1	NDC:68094-048-59	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	ANDA078912	03/22/2023	

Labeler - Precision Dose Inc. (035886746)

Revised: 11/2023

Precision Dose Inc.