

MUCUS- guaifenesin tablet, extended release
CHAIN DRUG MARKETING ASSOCIATION INC

Guaifenesin Extended-Release Tablets 600 mg

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

- 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 20-25°C (68-77°F)

Inactive ingredients

carbomer homopolymer type B; hypromellose, USP; magnesium stearate, NF; microcrystalline cellulose, NF; sodium starch glycolate, NF

Questions?

(1-800-406-7984)

You may also report side effects to this phone number.

Distributed by C.D.M.A., Inc.©
43157 W. Nine Mile
Novi, MI 48375

PRINCIPAL DISPLAY PANEL - 600 mg Tablet Blister Pack Carton

QUALITY CHOICE

NDC 63868-389-20

†Compare to
**Active Ingredient in
Mucinex®**

**Mucus Relief
Guaifenesin
Extended-Release
Tablets 600 mg**

Expectorant

12 Hour

- Relieves Chest Congestion
- Thins and Loosens Mucus
- Immediate and Extended Release

20 Extended-Release Tablets



MUCUS

guaifenesin tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-389
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 HOMO POLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZKN31)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3W0)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)

SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)

Product Characteristics

Color	WHITE	Score	no score
Shape	OVAL	Size	16mm
Flavor		Imprint Code	Mxeunic;600
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-389-20	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
NDA	NDA021282	02/08/2018	

Labeler - CHAIN DRUG MARKETING ASSOCIATION INC (011920774)

Establishment

Name	Address	ID/FEI	Business Operations
RECKITT BENCKISER HEALTHCARE INTERNATIONAL LTD		230780363	MANUFACTURE(63868-389)

Revised: 12/2018

CHAIN DRUG MARKETING ASSOCIATION INC