

**GUAIFENESIN EXTENDED RELEASE- guaifenesin tablet, extended release
OHM LABORATORIES INC**

GUAIFENESIN EXTENDED-RELEASE TABLETS, 1200 mg 14ct and 28ct

Drug Facts

Active ingredient (in each extended-release tablet)

Guaifenesin 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 the 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

- **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:

Sun Pharmaceutical Industries, Inc.

Cranbury, NJ 08512

Made in England

PRINCIPAL DISPLAY PANEL - 1200 mg Tablet Blister Pack Carton

† **Compare To**
the active ingredient of
Maximum Strength
Mucinex®

NDC 51660-072-86

ohm®

Maximum Strength

Guaifenesin

Extended-Release Tablets

1200 mg

Expectorant

12 Hour

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

28 Extended-Release Tablets

28 Extended-Release
Tablets

Maximum Strength

Guaifenesin Extended-Release Tablets

1200 mg

Expectorant

NDC 51660-072-06

Compare To
the active ingredient of
**Maximum Strength
Mucinex®**

ohm®

Maximum Strength

Guaifenesin Extended-Release Tablets

1200 mg

Expectorant

12 Hour

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



28 Extended-Release Tablets

28 Extended-Release
Tablets

ohm®

Maximum Strength
Guaifenesin
Extended-Release Tablets
1200 mg
Expectorant

Lot No.

Expiration Date:

NON VARNISH



5142032



GUAIFENESIN EXTENDED RELEASE

guaifenesin tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51660-072
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 HOMO POLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)				
hypromellose, unspecified (UNII: 3NXW29V3WO)				
magnesium stearate (UNII: 70097M6B0)				
microcrystalline cellulose (UNII: OP1R32D61U)				
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)				
Product Characteristics				
Color	WHITE	Score	no score	
Shape	OVAL	Size	22mm	
Flavor		Imprint Code	Mxeunic;1200	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51660-072-54	1 in 1 CARTON	12/10/2017	
1		14 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:51660-072-86	2 in 1 CARTON	12/10/2017	
2		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	
NDA	NDA021282	12/10/2017		

Labeler - OHM LABORATORIES INC (184769029)

Establishment

Name	Address	ID/FEI	Business Operations
RECKITT BENCKISER HEALTHCARE INTERNATIONAL LTD		230780363	MANUFACTURE(51660-072)

Revised: 11/2018

OHM LABORATORIES INC