GUAIFENESIN- guaifenesin tablet, extended release
OHM LABORATORIES 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:
Sun Pharmaceutical Industries, Inc.
Cranbury, NJ 08512

PRINCIPAL DISPLAY PANEL - 600 mg Tablet Blister Pack Carton

NDC 51660-070-41

†Compare To
the active ingredient of
Mucinex®

ohm®

Guaifenesin
Extended-Release Tablets
600 mg
Expectorant

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

40 Extended-Release Tablets

GUAIFENESIN

guaifenesin tablet, extended release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51660-070
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 CROSSLINKED) (UNII: HHT01ZNK31)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
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:51660-070-21	1 in 1 CARTON	02/08/2018	
1		20 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:51660-070-41	2 in 1 CARTON	02/08/2018	
2		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	01/08/2018	

Labeler - OHM LABORATORIES INC (184769029)

Establishment

Name	Address	ID/FEI	Business Operations
RECKITT BENCKISER HEALTHCARE INTERNATIONAL LTD		230780363	MANUFACTURE(51660-070)

Revised: 6/2019 OHM LABORATORIES INC