GUAIFENESIN AND DEXTROMETHORPHAN HBR- guaifenesin and dextromethorphan hbr tablet, extended release
OHM LABORATORIES INC

Guaifenesin and Dextromethorphan HBr

Drug Facts

Active ingredients (in each extended-release tablet)	***Purposes***
Dextromethorphan HBr 60 mg	Cough suppressant
Guaifenesin 1200 mg	Expectorant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily relieves:
  - cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
  - the intensity of coughing
  - the impulse to cough to help you get to sleep

Warnings

Do not use

- for children under 12 years of age
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

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)

When using this product

- do not use more than directed

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 timing of meals
- adults and children 12 years and older: 1 extended-release tablet every 12 hours; not more than 2 extended-release tablets in 24 hours
- children under 12 years of age: do not use

Other information

- Store between 20-25°C (68-77°F)

Inactive ingredients

carbomer homopolymer, colloidal silicon dioxide, hypromellose, magnesium stearate, maltodextrin, microcrystalline cellulose, povidone (K-30), stearic acid

Questions?

(1-800-406-7984)

You may also report side effects to this phone number.

Distributed by:
Ohm Laboratories Inc.
New Brunswick, NJ 08901

PRINCIPAL DISPLAY PANEL - 14 Tablet Blister Pack Carton

†Compare To
the active ingredients of
Maximum Strength
Mucinex® DM

NDC 51660-110-54

ohm®

Maximum Strength

Guaifenesin 1200 mg
& Dextromethorphan HBr 60 mg
Extended-Release Tablets

Expectorant & Cough Suppressant

12 Hour

- Controls Cough
- Thins and Loosens Mucus

- Immediate and Extended Release

14 Extended-Release Tablets

ohm®

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Tablet shown actual size

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& Dextromethorphan HBr 60 mg
Extended-Release Tablets
Expectorant & Cough Suppressant

PARENTS:
Learn about teen medicine abuse
www.StopMedicineAbuse.org

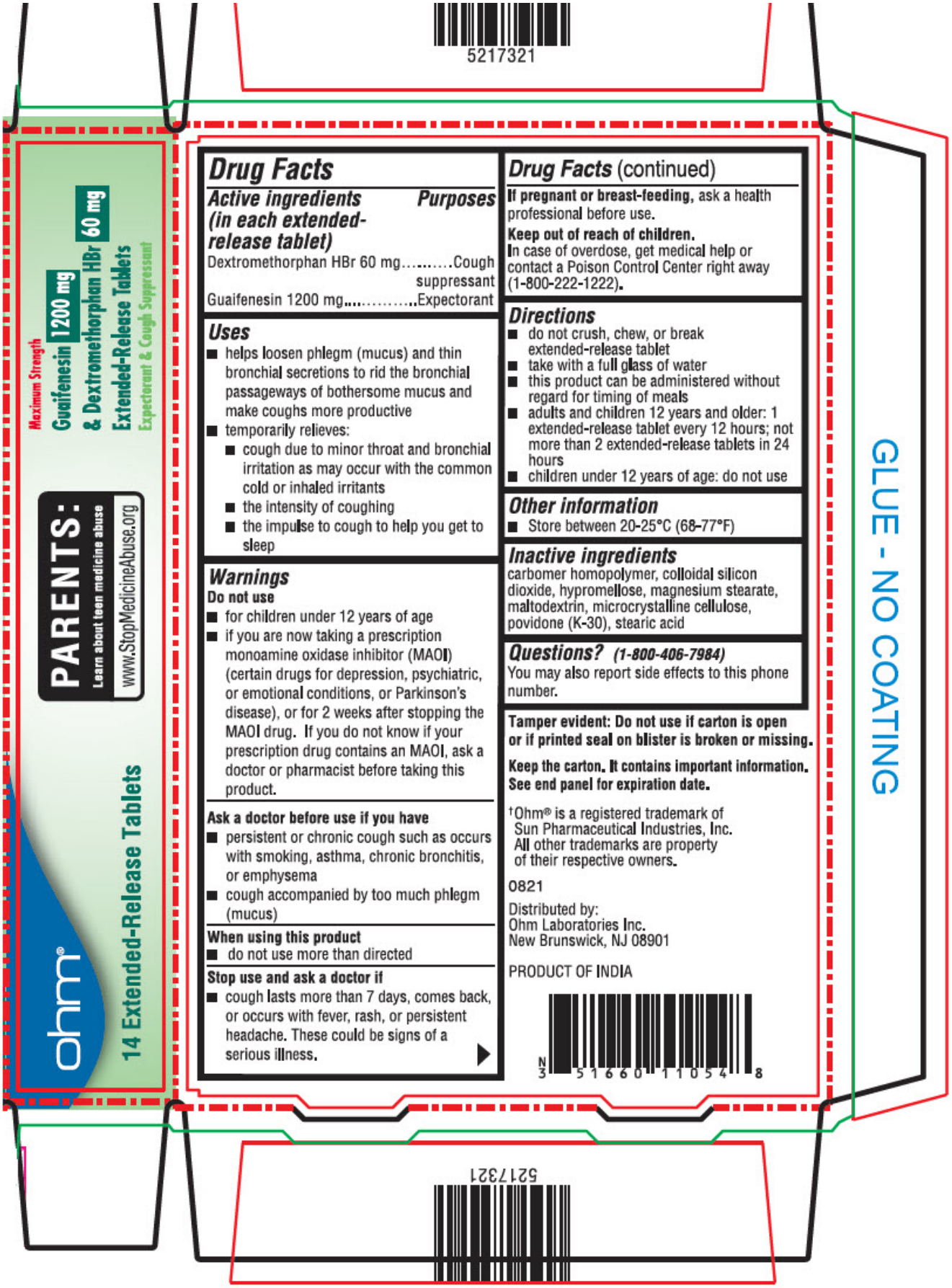
ohm®

14 Extended-Release Tablets

Lot No.

Expiration Date:

NON VARNISH



GUAIFENESIN AND DEXTROMETHORPHAN HBR

guaifenesin and dextromethorphan hbr tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51660-110
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	1200 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	60 mg

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
POVIDONE K30 (UNII: U725QWY32X)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	WHITE (off-white)	**Score**	no score
Shape	OVAL	**Size**	16mm
Flavor		**Imprint Code**	053
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51660-110-54	1 in 1 CARTON	07/01/2021	
1		14 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:51660-110-86	2 in 1 CARTON	07/01/2021	
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

ANDA	ANDA214781	07/01/2021	

Labeler - OHM LABORATORIES INC (184769029)

Registrant - SUN PHARMACEUTICAL INDUSTRIES, INC. (146974886)

Establishment

Name	Address	ID/FEI	Business Operations
Sun Pharmaceutical Industries Limited		650456002	MANUFACTURE(51660-110)

Revised: 8/2021 OHM LABORATORIES INC