

GUAIFENESIN AND DEXTROMETHORPHAN HYDROBROMIDE- guaifenesin and dextromethorphan hydrobromide tablet, extended release
OHM LABORATORIES INC

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

Drug Facts

<i>Active ingredients (in each extended-release tablet)</i>	<i>Purposes</i>
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 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 tablet every 12 hours; not more than 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/60 mg Tablet Blister Pack Carton

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

NDC 51660-073-86

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*

28 Extended-Release Tablets

ohm®

Maximum Strength

Guaifenesin 1200 mg
& Dextromethorphan HBr 60 mg

Extended-Release Tablets

Expectorant & Cough Suppressant

28 Extended-Release
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Maximum Strength
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ohm®

Maximum Strength

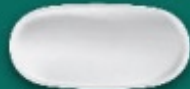
Guaifenesin 1200 mg
& Dextromethorphan HBr 60 mg

Extended-Release Tablets

Expectorant & Cough Suppressant

12 Hour

- Controls Cough
- Thins and Loosens Mucus
- Immediate and Extended Release



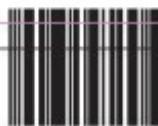
28 Extended-Release Tablets

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Lot No.

Expiration Date:

NON VARNISH



5142035

28 Extended-Release
Tablets

ohm®

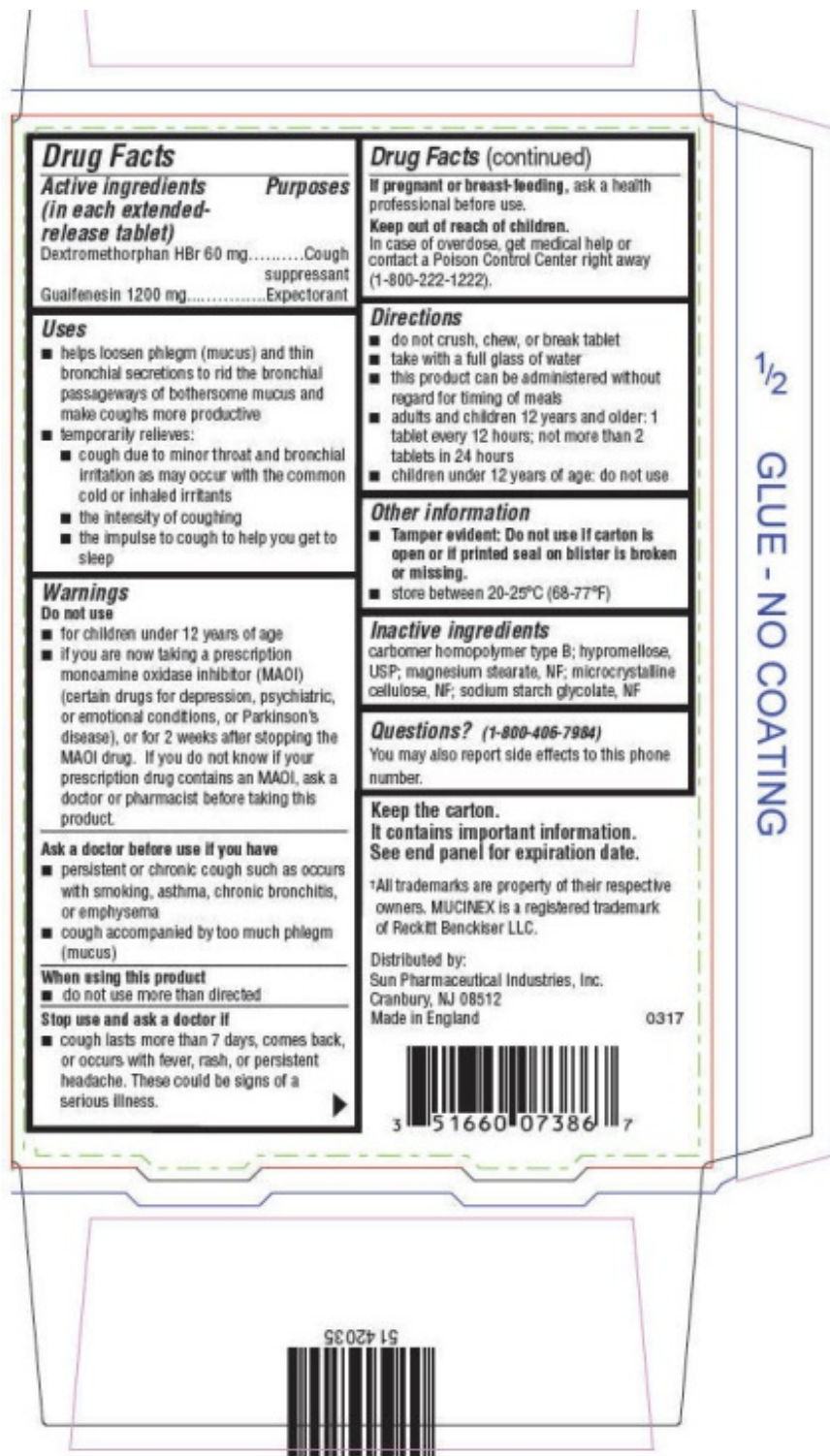
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PARENTS:
Learn about teen medicine abuse
www.StopMedicineAbuse.org

ohm®

28 Extended-Release
Tablets



GUAIFENESIN AND DEXTROMETHORPHAN HYDROBROMIDE

guaifenesin and dextromethorphan hydrobromide tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51660-073
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
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	22mm
Flavor		Imprint Code	xeunciM;1200
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51660-073-54	1 in 1 CARTON	12/10/2017	
1		14 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:51660-073-86	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	NDA021620	12/10/2017	

Labeler - OHM LABORATORIES INC (184769029)**Establishment**

Name	Address	ID/FEI	Business Operations
RECKITT BENCKISER HEALTHCARE INTERNATIONAL LTD		230780363	MANUFACTURE(51660-073)