

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

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**Guaifenesin 600 mg & Dextromethorphan HBr 30 mg Extended-Release Tablets**

***Drug Facts***

<b><i>Active ingredients (in each extended-release tablet)</i></b>	<b><i>Purposes</i></b>
Dextromethorphan HBr 30 mg	Cough suppressant
Guaifenesin 600 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 or 2 tablets every 12 hours; not more than 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 - 40 Tablet Blister Pack Carton**

†Compare To  
the active ingredients of  
Mucinex<sup>®</sup> DM

NDC 51660-054-41

ohm<sup>®</sup>

Guaifenesin 600 mg  
& Dextromethorphan HBr 30 mg  
Extended-Release Tablets

Expectorant & Cough Suppressant

12 Hour

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

40 Extended-Release Tablets

ohm<sup>®</sup>

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**PARENTS:**  
Learn about teen medicine abuse  
[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)

Distributed by:  
Sun Pharmaceutical Industries, Inc.  
Cranbury, NJ 08512  
Made in England

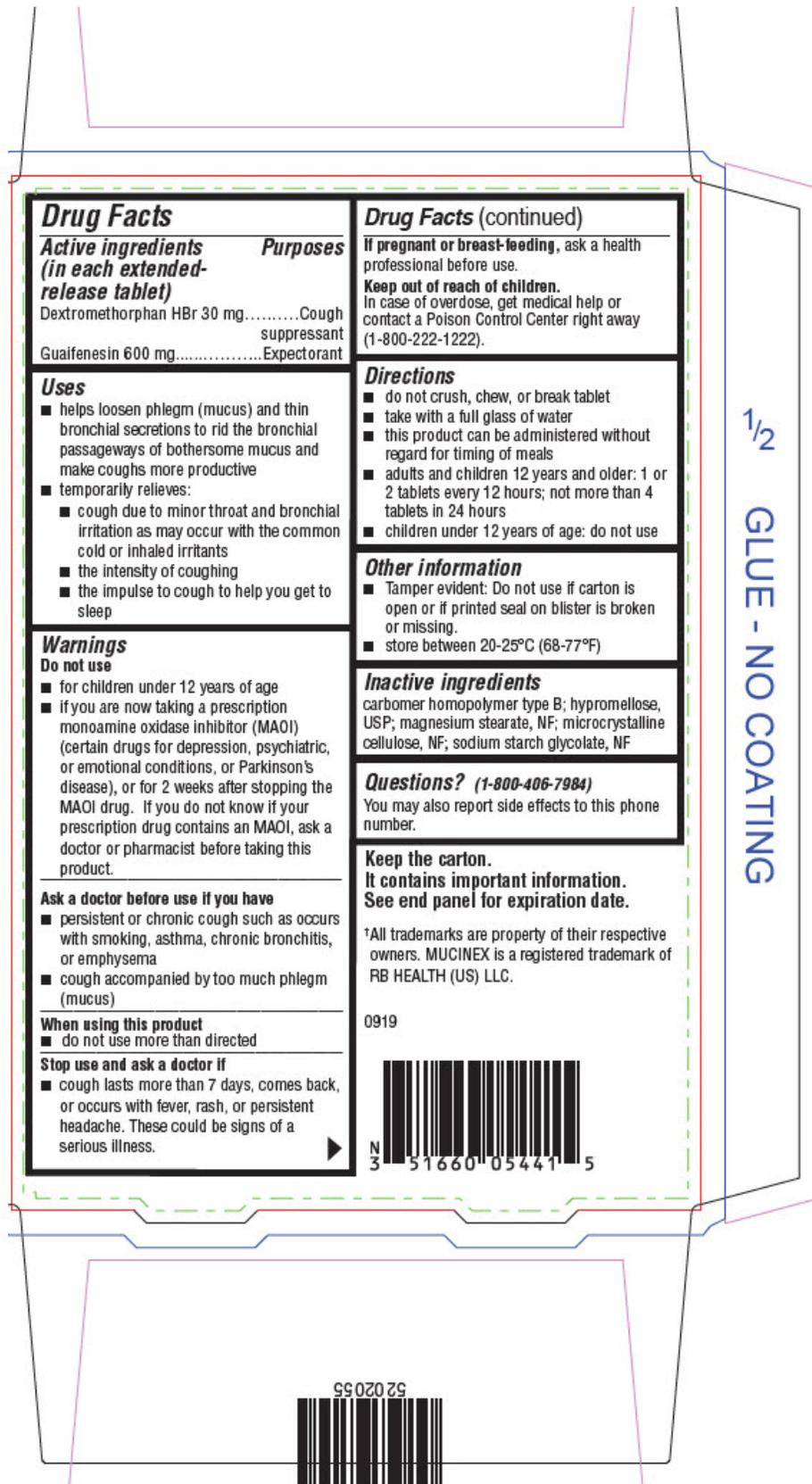
Lot No.

Expiration Date:

**NON VARNISH**



5202055



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**Keep the carton.**  
**It contains important information.**  
**See end panel for expiration date.**

\*All trademarks are property of their respective owners. MUCINEX is a registered trademark of RB HEALTH (US) LLC.

0919



1/2

GLUE - NO COATING

<b>GUAIFENESIN AND DEXTROMETHORPHAN HYDROBROMIDE</b>			
guaifenesin and dextromethorphan hydrobromide tablet, extended release			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51660-054

<b>Route of Administration</b>	ORAL
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### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Guaifenesin</b> (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	600 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>CARBOMER HOMO POLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: HHT01ZNK31)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)	

### Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	22mm
<b>Flavor</b>		<b>Imprint Code</b>	xeunciM;1200
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51660-054-41	1 in 1 CARTON	10/01/2019	
1		40 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	10/01/2019	

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

### Establishment

Name	Address	ID/FEI	Business Operations
RECKITT BENCKISER HEALTHCARE INTERNATIONAL LTD		230780363	MANUFACTURE(51660-054)