GUAIFENESIN AND DEXTROMETHORPHAN HYDROBROMIDE- guaifenesin and dextromethorphan hydrobromide tablet, extended release
CHAIN DRUG MARKETING ASSOCIATION INC

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

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 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.

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43157 W. Nine Mile
Novi, MI 48375

PRINCIPAL DISPLAY PANEL - 1200 mg/60 mg Tablet Blister Pack Carton

NDC 63868-391-14

QC®
QUALITY
CHOICE

†Compare to
Active Ingredients in
Maximum Strength
Mucinex® DM

Maximum Strength

Mucus Relief DM

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

Maximum Strength
Mucus Relief DM
Guaifenesin 1200 mg & Dextromethorphan HBr 60 mg
Extended-Release Tablets
Expectorant & Cough Suppressant

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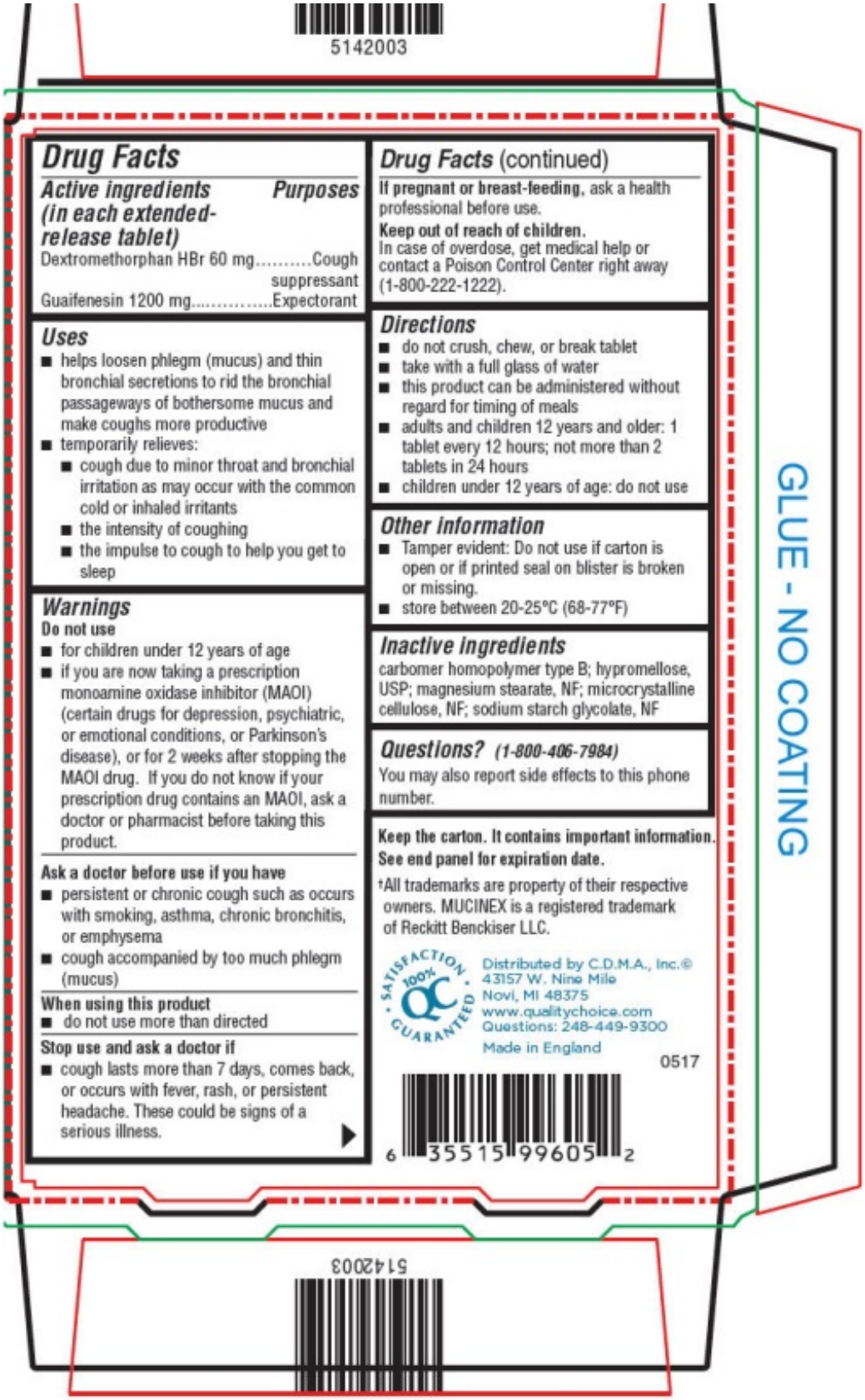
14 Extended-Release Tablets

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

Maximum Strength
Mucus Relief DM
Guaifenesin 1200 mg & Dextromethorphan HBr 60 mg
Extended-Release Tablets
Expectorant & Cough Suppressant

Lot No.
Expiration Date:

NON VARNISH



GUAIFENESIN AND DEXTROMETHORPHAN HYDROBROMIDE

guaifenesin and dextromethorphan hydrobromide tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63868-391
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 OR ALLYL SUCROSE CROSSLINKED) (UNII: K6MOM3T5YL)	
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**	Mucinex;1200
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-391-14	2 in 1 CARTON	12/10/2017	
1		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 - CHAIN DRUG MARKETING ASSOCIATION INC (011920774)

Establishment

Name	Address	ID/FEI	Business Operations
RECKITT BENCKISER HEALTHCARE INTERNATIONAL LTD		230780363	MANUFACTURE(63868-391)

Revised: 10/2017 CHAIN DRUG MARKETING ASSOCIATION INC