MUCUS RELIEF DM COUGH- dextromethorphan hbr, guaifenesin tablet, film coated
Major Pharmaceuticals

Major 44-533

Active ingredients (in each immediate-release tablet)

Dextromethorphan HBr 20 mg
Guaifenesin 400 mg

Purpose

Cough suppressant
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 associated with the common cold
  - the intensity of coughing
  - the impulse to cough to help you get to sleep

Warnings

Do not use

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

- cough accompanied by too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema

When using this product

do not exceed recommended dosage.

Stop use and ask a doctor if

cough persists more than 7 days, tends to recur, or is accompanied by a fever, rash, or persistent headache. These could be signs of a serious condition.

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 (1-800-222-1222) right away.

Directions

- take with a full glass of water
- adults and children 12 years and over: 1 tablet every 4 hours. Do not take more than 6 tablets in 24 hours.
- children under 12 years: do not use

Other information

- store at 25ºC (77ºF); excursions permitted between 15°-30°C (59°-86°F)
- use by expiration date on package

Inactive ingredients

D&C yellow #10 aluminum lake, hypromellose, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, povidone, silicon dioxide, sodium starch glycolate, stearic acid

Questions or comments?

(800) 616-2471

Principal Display Panel

MAJOR®

NDC 0904-6816-52

MucusRelief
DM COUGH

Dextromethorphan HBr, 20 mg
Guaifenesin, 400 mg

Cough Suppressant
Expectorant

• Controls Cough
• Thins and Loosens Mucus

Immediate Release

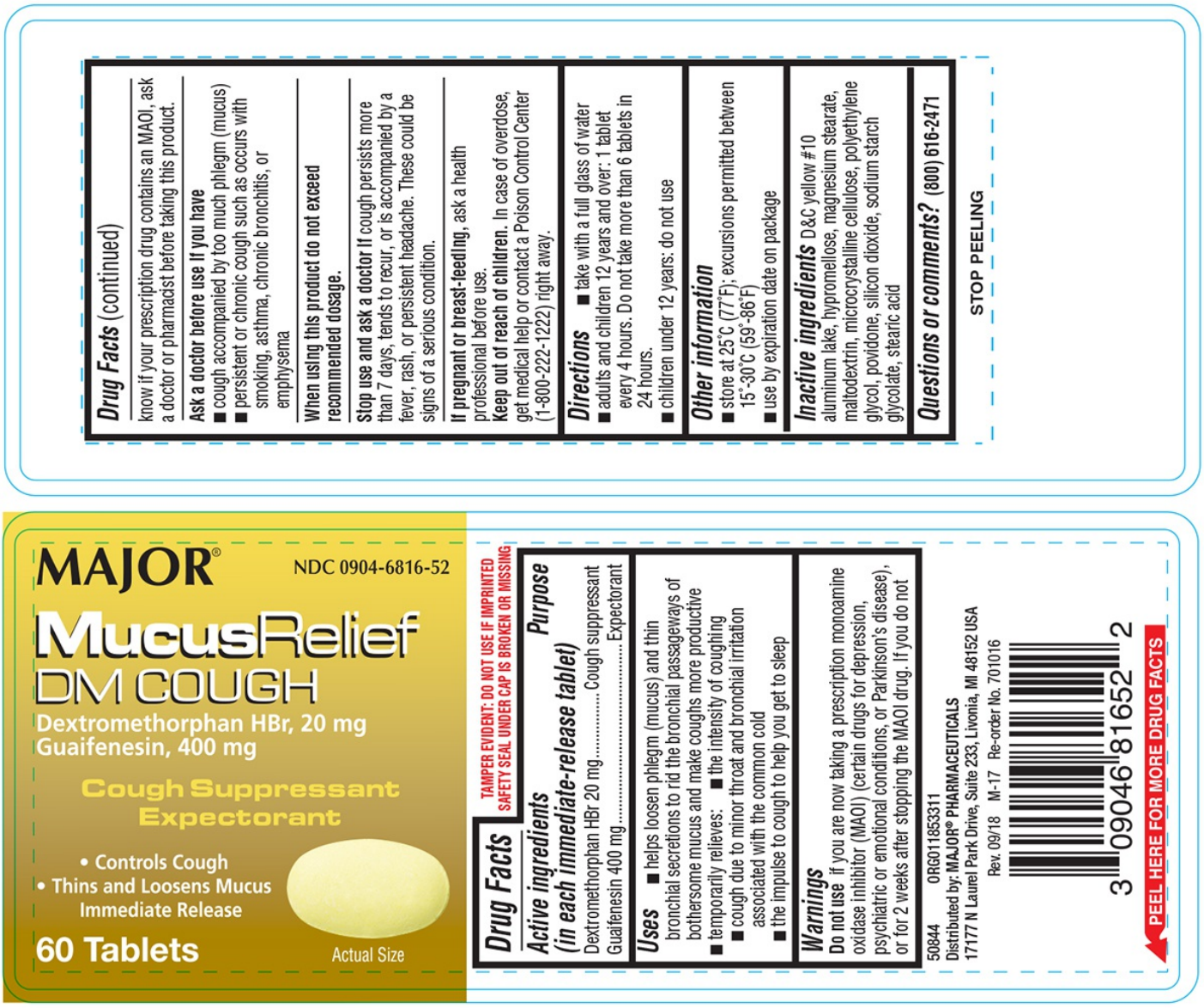
60 Tablets

Actual Size

TAMPER EVIDENT: DO NOT USE IF IMPRINTED
SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

50844 ORG011853311
Distributed by: **MAJOR® PHARMACEUTICALS**
17177 N Laurel Park Drive, Suite 233, Livonia, MI 48152 USA

Rev. 09/18 M-17 Re-order No. 701016



Major 44-533

MUCUS RELIEF DM COUGH

dextromethorphan hbr, guaifenesin tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0904-6816

Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg

Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	yellow	**Score**	2 pieces
Shape	OVAL	**Size**	16mm
Flavor		**Imprint Code**	44;533
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-6816-52	60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/19/2018	
2	NDC:0904-6816-46	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/19/2018	04/03/2021

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	12/19/2018	

Labeler - Major Pharmaceuticals (191427277)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(0904-6816)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(0904-6816) , pack(0904-6816)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(0904-6816)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(0904-6816)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(0904-6816)