

021620_MUCINEX DM_ORIGINAL_APPROVAL_PKG.PDF

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

21-620

Trade Name: Mucinex DM Extended Release Tablets

Generic Name: Guaifenesin/Dextromethorphan HBr Extend Release
(ER)

Sponsor: Adams Laboratories

Approval Date: April 29, 2004

Indications: 12 hour expectorant and antitussive for treating cold,
cough, and allergy patients.

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-620

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**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-620

APPROVAL LETTER



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-620

Adams Respiratory Therapeutics
14841 Sovereign Road
Fort Worth, TX 76155-2645

Attention: Daniel F. Wagner
Director, Clinical and Regulatory Affairs

Dear Mr. Wagner:

Please refer to your June 30, 2003, new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Mucinex TMDM (guaifenesin and dextromethorphan) Extended-release Tablets.

We acknowledge receipt of your submissions dated July 14, August 14 and 25, and November 3 and 11, 2003, and January 30, February 18 and 27, and March 3, 12, and 25, 2004.

This new drug application provides for the use of Mucinex TMDM (guaifenesin and dextromethorphan HBr) Extended-release Tablets as an expectorant and antitussive.

We completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (immediate container, carton, and tray labels submitted March 12, 2004), and must be in the "Drug Facts" format (21 CFR 201.66). Marketing the product with FPL that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-620.**" Approval of this submission by FDA is not required before the labeling is used.

We have the following comments.

1. You have agreed to monitor for adverse events related to Mucinex[®] DM abuse as outlined in your March 3, 2004, submission. If a safety signal is noted in postmarketing surveillance, you have agreed to devise and implement a risk management plan to reduce rates of abuse of Mucinex[®] DM. If a safety signal is detected, you should consider whether the drug product should be placed behind the pharmacy counter to deter individuals from purchasing large quantities at one time.

2. The word "NEW" must be deleted from the PDP six months after introduction into the market place.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for patients less than 12 years of age for this application.

In addition, we request that you submit two copies of the introductory promotional materials you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Please send one of the copies to the Division of Pulmonary and Allergy Drug Products and the other copy, along with the labeling, to Division of Over-the-Counter Drug Products, HFD-560.

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

Oversight of this application is being transferred to the Division of Over-the-Counter Drug Products.

If you have any questions, call Leah Cutter, Ph.D., Regulatory Project Manager at (301) 827-2248.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, M.D., Ph.D.
Director
Division of Pulmonary and Allergy Drug
Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Sincerely,

{See appended electronic signature page}

Charles Ganley, M.D.
Director
Division of Over-the Counter Drug
Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Enclosure Approved labeling

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Badrul Chowdhury
4/28/04 03:26:40 PM

Charles Ganley
4/29/04 03:57:18 PM

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-620

APPROVED LABELING

NDC 63824-056-82

Mucinex^{DM}

600 mg guaifenesin and
30 mg dextromethorphan HBr
extended-release bi-layer tablets

EXPECTORANT AND
COUGH SUPPRESSANT

2 EXTENDED-RELEASE BI-LAYER TABLETS

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: one or two tablets every 12 hours; not more than 4 tablets in 24 hours
- children under 12 years of age: do not use

PHYSICIAN
SAMPLE-
NOT TO BE SOLD

Adams[®]
LABORATORIES, INC.

Fort Worth, Texas 76155

US Pat. 6,372,252 B1

3105602 030904

3-63824-05682-1

15/16"

4 1/4"

MUCINEX DM 600/30 mg (2 count) LABEL

Heading:

8 pt. Helvetica Bold
Italic, left justified

Bullets:

5 pt. solid square
Zapf Dingbats

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: one or two tablets every 12 hours; not more than 4 tablets in 24 hours
- children under 12 years of age: do not use

Body text:

6 pt. Helvetica Regular
with 6.5 pt. leading,
left justified

2.5 pt. box barline

NDC 63824-056-20

Mucinex^{DM}

600 mg guaifenesin and
30 mg dextromethorphan HBr
extended-release bi-layer tablets

EXPECTORANT AND
COUGH SUPPRESSANT

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: one or two tablets every 12 hours; not more than 4 tablets in 24 hours
- children under 12 years of age: do not use

US Pat. 8,372,252 B1

Adams[®]

LABORATORIES, INC. Fort Worth, Texas 76155

3-63824-056-20-3

Please visit our Web site:
www.mucinex.com
or call 1-866-MUCINEX
(1-866-682-4639)

20 EXTENDED-RELEASE BI-LAYER TABLETS

3005820
030904

© 2004 Adams Laboratories, Inc.

5 1/4"

2"

MUCINEX DM 600/30 mg (20 count) LABEL

Heading:
8 pt. Helvetica Bold
Italic, left justified

Bullets:
5 pt. solid square
Zapf Dingbats

-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: one or two tablets every
12 hours; not more than 4 tablets
in 24 hours
■ children under 12 years of age:
do not use

Body text:
6 pt. Helvetica Regular
with 6.5 pt. leading,
left justified

-2.5 pt. box barline

NDC 63824-056-40

Mucinex^{DM}
600 mg guaifenesin and
30 mg dextromethorphan HBr
extended-release bi-layer tablets
EXPECTORANT AND
COUGH SUPPRESSANT

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: one or two tablets every 12 hours; not more than 4 tablets in 24 hours
- children under 12 years of age: do not use

3-63824-056-40-1

*Please visit our Web site:
www.mucinex.com
or call 1-866-MUCINEX
(1-866-682-4639)*

US Pat. 6,372,252 B1

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LABORATORIES, INC. Fort Worth, Texas 76155

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3005640
030904

40 EXTENDED-RELEASE BI-LAYER TABLETS

5 1/4"

2"

MUCINEX DM 600/30 mg (40 count) LABEL

Heading:
8 pt. Helvetica Bold
Italic, left justified

Bullets:
5 pt. solid square
Zapf Dingbats

-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: one or two tablets every
12 hours; not more than 4 tablets
in 24 hours
■ children under 12 years of age:
do not use

Body text:
6 pt. Helvetica Regular
with 6.5 pt. leading,
left justified

2.5 pt. box barline

NDC 63824-037-82

Mucinex^{DM}

1200 mg guaifenesin and
60 mg dextromethorphan HBr
extended-release bi-layer tablets

**EXPECTORANT AND
COUGH SUPPRESSANT**

2 EXTENDED-RELEASE BI-LAYER TABLETS

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: one tablet every 12 hours; not more than 2 tablets in 24 hours
- children under 12 years of age: do not use

PHYSICIAN
SAMPLE-
NOT TO BE SOLD

Adams[®]
LABORATORIES, INC.

Fort Worth, Texas 76155
US Pat. 6,372,252 B1

3103702 030904

3-63824-03782-0

15/16"

4 1/4"

MUCINEX DM 1200/60 mg (2 count) LABEL

Heading:
8 pt. Helvetica Bold
Italic, left justified

Bullets:
5 pt. solid square
Zapf Dingbats

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: one tablet every 12 hours; not more than 2 tablets in 24 hours
- children under 12 years of age: do not use

Body text:
6 pt. Helvetica Regular
with 6.5 pt. leading,
left justified

-2.5 pt. box barline

NDC 63824-037-01

Mucinex-D^{DM}

1200 mg guaifenesin and
60 mg dextromethorphan HBr
extended-release bi-layer tablets

**EXPECTORANT AND
COUGH SUPPRESSANT**



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: one tablet every 12 hours, not more than 2 tablets in 24 hours
- children under 12 years of age: do not use

US Pat. 6,372,252 B1

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3-63824-037-01-1

*Please visit our Web site:
www.mucinex.com
or call 1-866-MUCINEX
(1-866-682-4639)*

3003701
030804

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5 1/4"

2"

MUCINEX DM 1200/60 mg (10 count) LABEL

Heading:
8 pt. Helvetica Bold
Italic, left justified

Bullets:
5 pt. solid square
Zapf Dingbats

-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: one tablet every 12 hours;
not more than 2 tablets in 24 hours
■ children under 12 years of age,
do not use

Body text:
6 pt. Helvetica Regular
with 6.5 pt. leading,
left justified

2.5 pt. box barline

NDC 63824-037-20

Mucinex^{DM}

1200 mg guaifenesin and
60 mg dextromethorphan HBr
extended-release bi-layer tablets

**EXPECTORANT AND
COUGH SUPPRESSANT**



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: one tablet every 12 hours; not more than 2 tablets in 24 hours
- children under 12 years of age: do not use

US Pat. 6,372,252 B1

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LABORATORIES, INC. Fort Worth, Texas 76155

3-63824-037-20-2

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(1-866-682-4639)*

3003720
630304

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5 1/4"

2"

MUCINEX DM 1200/60 mg (20 count) LABEL

Heading:
8 pt. Helvetica Bold
Italic, left justified

Bullets:
5 pt. solid square
Zapf Dingbats

-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: one tablet every 12 hours;
not more than 2 tablets in 24 hours
■ children under 12 years of age:
do not use

Body text:
6 pt. Helvetica Regular
with 6.5 pt. leading,
left justified

-2.5 pt. box barline

MUCINEX DM 600/30 mg SAMPLE TRAY

Title:
14 pt. Helvetica Bold
Italic, left justified

Headings:
8 pt. Helvetica Bold
Italic, left justified

Bullets:
5 pt. solid square
Zapf Dingbats

Subheadings:
6 pt. Helvetica Bold
left justified

Graphic leading
to next panel

Drug Facts

Active ingredients (in each extended-release bi-layer tablet)

Dextromethorphan HBr 30 mg	Cough suppressant
Guafenesin 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 a 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)

Drug Facts (continued)

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

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: one or two 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 seal on bottle printed "SEALED FOR YOUR PROTECTION" is broken or missing
- store at 20-25°C (68-77°F)
- see bottom of bottle for lot code and expiration date

Inactive ingredients carbomer 934P, NF; D & C yellow #10 aluminum lake; hypromellose, USP; magnesium stearate, NF; microcrystalline cellulose, NF; sodium starch glycolate, NF

Right justified
Title for continued panel:
8 pt. Helvetica Bold Italic

8 pt. Helvetica Regular

0.5 pt. hairline

2.5 pt. barline

Body text:
6 pt. Helvetica Regular
with 6.5 pt. leading,
left justified

2.5 pt. box barline

1 3/4"
3 1/4"

Mucinex^{DM}
600 mg guaifenesin and
30 mg dextromethorphan HBr
extended-release bi-layer tablets
EXPECTORANT AND
COUGH SUPPRESSANT
20 EXTENDED-RELEASE
BI-LAYER TABLETS

Drug Facts (continued)

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.

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: one or two 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 seal on bottle printed "SEALED for YOUR PROTECTION" is broken or missing
- store at 20-25°C (68-77°F)
- see bottom of bottle for lot code and expiration date

Inactive ingredients carboxer 934P, NF; D&C yellow #10 aluminum lake; hypromellose, USP; magnesium stearate, NF; microcrystalline cellulose, NF; sodium starch glycolate, NF

NEW

NEW

Mucinex^{DM}
600 mg guaifenesin and
30 mg dextromethorphan HBr
extended-release bi-layer tablets
EXPECTORANT AND
COUGH SUPPRESSANT

Please visit our Web site:
www.mucinex.com

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NEW

NDC 63824-056-20

NEW

Mucinex^{DM}
600 mg guaifenesin and
30 mg dextromethorphan HBr
extended-release bi-layer tablets
EXPECTORANT AND
COUGH SUPPRESSANT

20 EXTENDED-RELEASE
BI-LAYER TABLETS

039904
2005620

NEW

Drug Facts

Active ingredients	Purpose
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 a 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)

3-63824-056-20-3

MUCINEX DM 600/30 mg (20 count) CARTON

Title:
14 pt. Helvetica Bold
Italic, left justified

Headings:
8 pt. Helvetica Bold
Italic, left justified

Bullets:
5 pt. solid square
Zapf Dingbats

Subheadings:
6 pt. Helvetica Bold
left justified

Graphic leading
to next panel

Drug Facts	
Active ingredients <i>(in each extended-release bi-layer tablet)</i>	Purpose
Dextromethorphan HBr 30 mg..... Cough suppressant	
Guaifenesin 600 mg..... Expectorant	
Uses	
<ul style="list-style-type: none"> ■ helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive ■ temporarily relieves: <ul style="list-style-type: none"> ■ 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	
<ul style="list-style-type: none"> ■ 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 a MAOI, ask a doctor or pharmacist before taking this product. 	
Ask a doctor before use if you have	
<ul style="list-style-type: none"> ■ persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema ■ cough accompanied by too much phlegm (mucus) > 	

Right justified

Title for continued panel:
8 pt. Helvetica Bold Italic

Drug Facts (continued)
When using this product
<ul style="list-style-type: none"> ■ do not use more than directed
Stop use and ask a doctor if
<ul style="list-style-type: none"> ■ 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.
Directions
<ul style="list-style-type: none"> ■ 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: one or two tablets every 12 hours; not more than 4 tablets in 24 hours ■ children under 12 years of age: do not use
Other information
<ul style="list-style-type: none"> ■ tamper evident: do not use if seal on bottle printed "SEALED for YOUR PROTECTION" is broken or missing ■ store at 20-25°C (68-77°F) ■ see bottom of bottle for lot code and expiration date
Inactive ingredients
<ul style="list-style-type: none"> ■ carboxymethylcellulose, NF; ■ D&C yellow #10 aluminum lake, hypromellose, USP; ■ magnesium stearate, NF; microcrystalline cellulose, NF; ■ sodium starch glycolate, NF

8 pt. Helvetica Regular

0.5 pt. hairline

2.5 pt. barline

Body text:
6 pt. Helvetica Regular
with 6.5 pt. leading,
left justified

2.5 pt. box barline

10 EXTENDED-RELEASE BI-LAYER TABLETS

600 mg guaifenesin and 30 mg dextromethorphan HBr extended-release bi-layer tablets

Mucinex^{DM}

NEW

Drug Facts (continued)

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

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: one or two 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 seal on bottle printed "SEALED FOR YOUR PROTECTION" is broken or missing
store at 20-25°C (68-77°F)
see bottom of bottle for lot code and expiration date

Inactive ingredients carboxer 934P, NF; D&C yellow #10 aluminum lake, hypromellose, USP; magnesium stearate, NF; microcrystalline cellulose, NF; sodium starch glycolate, NF

NEW

Mucinex^{DM}

600 mg guaifenesin and 30 mg dextromethorphan HBr extended-release bi-layer tablets

EXPECTORANT AND COUGH SUPPRESSANT

Please visit our Web site: www.mucinex.com

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Fort Worth, Texas 76155
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US Pat. 6,372,252 B1

NEW

NDC 63824-056-40

Mucinex^{DM}

600 mg guaifenesin and 30 mg dextromethorphan HBr extended-release bi-layer tablets

EXPECTORANT AND COUGH SUPPRESSANT

10 EXTENDED-RELEASE BI-LAYER TABLETS

Drug Facts

Active ingredients Purpose
Dextromethorphan HBr 30 mg Cough suppressant
Guaifenesin 600 mg Expectarant

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 a 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)

3-63824-056-40-1

MUCINEX DM 600/30 mg (40 count) CARTON

Title:
14 pt. Helvetica Bold
Italic, left justified

Headings:
8 pt. Helvetica Bold
Italic, left justified

Bullets:
5 pt. solid square
Zapf Dingbats

Subheadings:
6 pt. Helvetica Bold
left justified

Graphic leading
to next panel

Right justified

Drug Facts	
Active ingredients <i>(in each extended-release bi-layer tablet)</i>	Purpose
Dextromethorphan HBr 30 mg..... Cough suppressant	
Guafenesin 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 a 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) ▶	

Title for continued panel:
8 pt. Helvetica Bold Italic

Drug Facts (continued)
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.
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: one or two 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 seal on bottle printed "SEALED for YOUR PROTECTION" is broken or missing
■ store at 20-25°C (68-77°F)
■ see bottom of bottle for lot code and expiration date
Inactive ingredients carbomer 934P, NF; D&C yellow #10 aluminum lake; hypromellose, USP; magnesium stearate, NF; microcrystalline cellulose, NF; sodium starch glycolate, NF

Title for continued panel:
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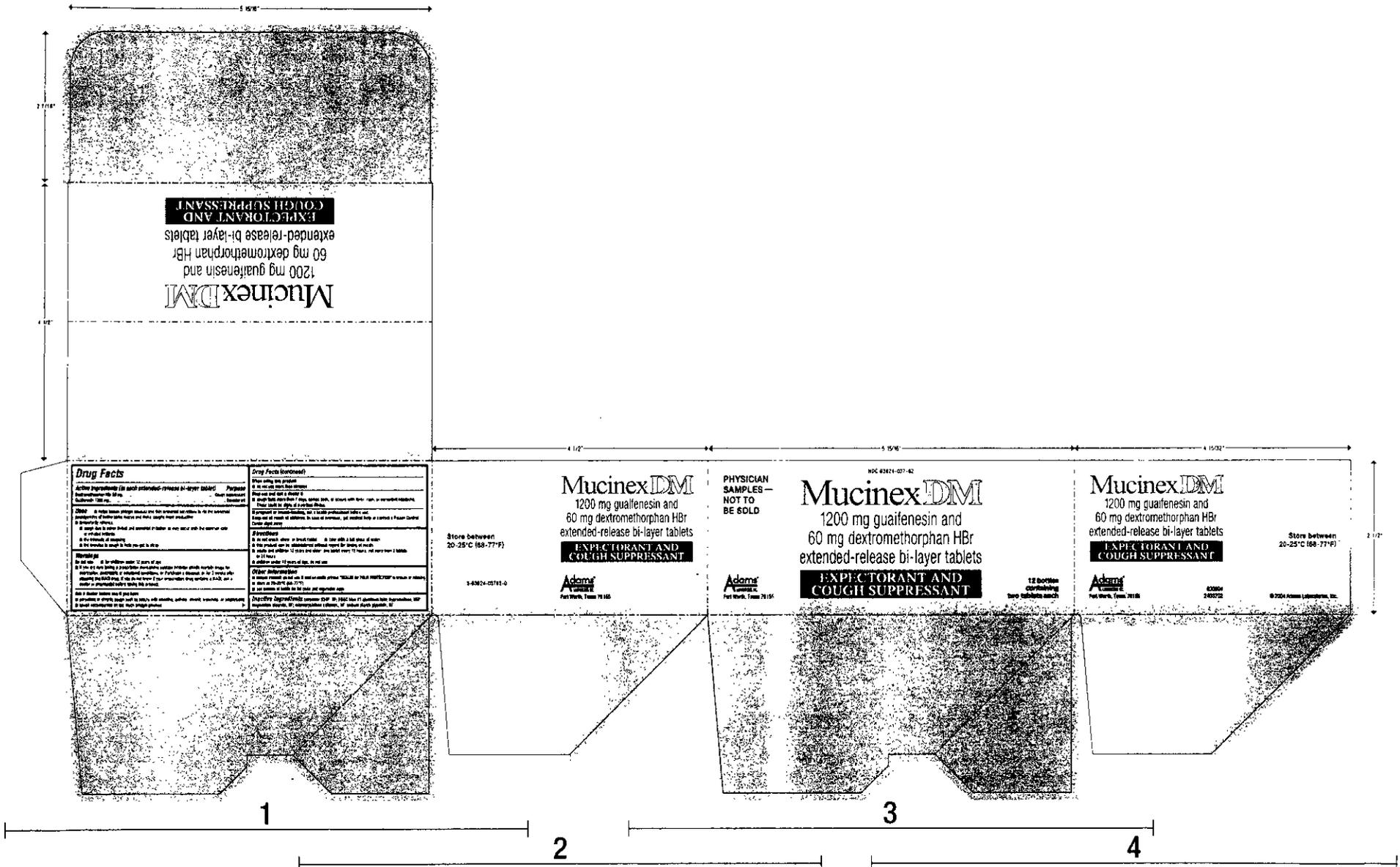
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Body text:
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with 6.5 pt. leading,
left justified

2.5 pt. box barline

FOR LAYOUT PURPOSES ONLY



MUCINEX DM 1200/60 mg SAMPLE TRAY

Title:
14 pt. Helvetica Bold
Italic, left justified

Headings:
8 pt. Helvetica Bold
Italic, left justified

Bullets:
5 pt. solid square
Zapf Dingbats

Subheadings:
6 pt. Helvetica Bold
left justified

Graphic leading
to next panel

<p>Drug Facts</p> <p>Active ingredients (in each extended-release bi-layer tablet)</p> <table border="0"> <tr> <td>Dextromethorphan HBr 60 mg</td> <td>Cough suppressant</td> </tr> <tr> <td>Guafenesin 1200 mg</td> <td>Expectorant</td> </tr> </table>		Dextromethorphan HBr 60 mg	Cough suppressant	Guafenesin 1200 mg	Expectorant	<p>Drug Facts (continued)</p> <p>When using this product</p> <ul style="list-style-type: none"> ■ do not use more than directed <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> ■ cough lasts more than 7 days, comes back, or occurs with fever, rash, or persistent headache. These could be signs of a serious illness. <p>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.</p> <p>Directions</p> <ul style="list-style-type: none"> ■ 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: one tablet every 12 hours; not more than 2 tablets in 24 hours ■ children under 12 years of age: do not use <p>Other information</p> <ul style="list-style-type: none"> ■ tamper evident: do not use if seal on bottle printed "SEALED FOR YOUR PROTECTION" is broken or missing ■ store at 20-25°C (68-77°F) ■ see bottom of bottle for lot code and expiration date <p>Inactive ingredients carbomer 934P, NF; FD&C blue #1 aluminum lake; hypromellose, USP; magnesium stearate, NF; microcrystalline cellulose, NF; sodium starch glycolate, NF</p>
Dextromethorphan HBr 60 mg	Cough suppressant					
Guafenesin 1200 mg	Expectorant					
<p>Uses</p> <ul style="list-style-type: none"> ■ helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive <p>temporarily relieves:</p> <ul style="list-style-type: none"> ■ 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 						
<p>Warnings</p> <p>Do not use</p> <ul style="list-style-type: none"> ■ 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 a MAOI, ask a doctor or pharmacist before taking this product. <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> ■ persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema ■ cough accompanied by too much phlegm (mucus) 						

Right justified

Title for continued panel:
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8 pt. Helvetica Regular

0.5 pt. hairline

2.5 pt. barline

Body text:
6 pt. Helvetica Regular
with 6.5 pt. leading,
left justified

2.5 pt. box barline

1 3/4"

3 1/4"

10 EXTENDED-RELEASE
BI-LAYER TABLETS

Mucinex^{DM}
1200 mg guaifenesin and
60 mg dextromethorphan HBr
extended-release bi-layer tablets
EXPECTORANT AND
COUGH SUPPRESSANT

NEW

Drug Facts (continued)

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.

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:
one 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 seal on bottle printed
"SEALED FOR YOUR PROTECTION" is broken or missing
- store at 20-25°C (68-77°F)
- see bottom of bottle for lot code and expiration date

Inactive ingredients carboner 934P, NF;
FD&C blue #1 aluminum lake; hydroxypropylcellulose, USP;
magnesium stearate, NF; microcrystalline cellulose, NF;
sodium starch glycolate, NF

NEW

Mucinex^{DM}

1200 mg guaifenesin and
60 mg dextromethorphan HBr
extended-release bi-layer tablets

EXPECTORANT AND
COUGH SUPPRESSANT

Please visit our Web site:
www.mucinex.com

Adams[®]
LABORATORIES
Ft. Worth, Texas 76155
© 2004 Adams Laboratories, Inc.
US Pat. 6,372,252 B1

900904
2003701

NDC 63824-037-01

NEW

Mucinex^{DM}

1200 mg guaifenesin and
60 mg dextromethorphan HBr
extended-release bi-layer tablets

EXPECTORANT AND
COUGH SUPPRESSANT

10 EXTENDED-RELEASE
BI-LAYER TABLETS

3-63824-037-01-1

1 3/4"

Drug Facts

Active ingredients Purpose
(in each extended-release
bi-layer tablet)
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 a 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) ▶

MUCINEX DM 1200/60 mg (10 count) CARTON

Title:
14 pt. Helvetica Bold
Italic, left justified

Headings:
8 pt. Helvetica Bold
Italic, left justified

Bullets:
5 pt. solid square
Zapf Dingbats

Subheadings:
6 pt. Helvetica Bold
left justified

Graphic leading
to next panel

Drug Facts

Active ingredients (in each extended-release bi-layer tablet)	Purpose
Dextromethorphan HBr 60 mg.....	Cough suppressant
Guafenesin 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 a 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) ▶

Right justified

Title for continued panel:
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0.5 pt. hairline

2.5 pt. barline

Body text:
6 pt. Helvetica Regular
with 6.5 pt. leading,
left justified

2.5 pt. box barline

Drug Facts (continued)

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.

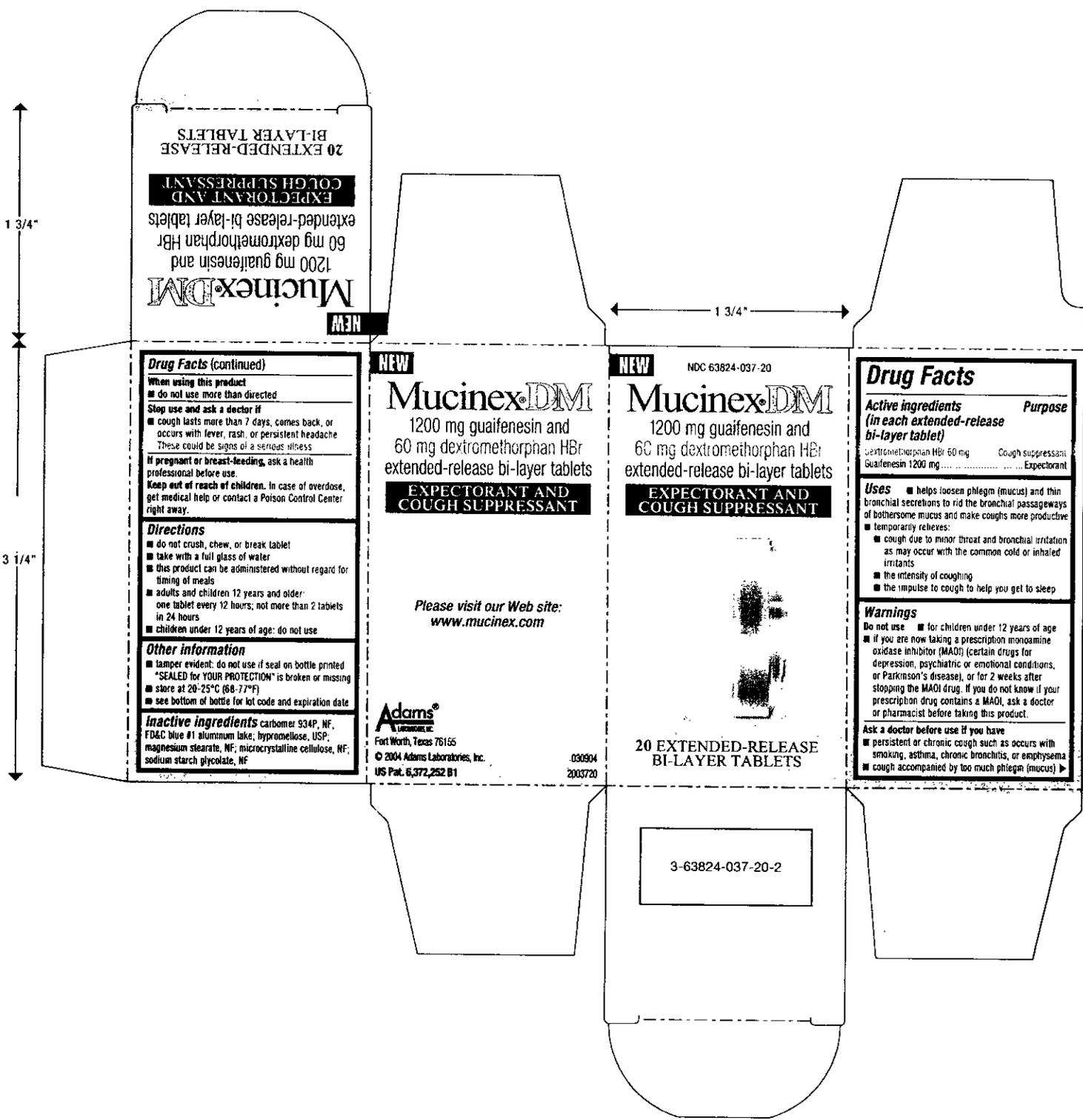
Directions

- 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: one 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 seal on bottle printed "SEALED for YOUR PROTECTION" is broken or missing
- store at 20-25°C (68-77°F)
- see bottom of bottle for lot code and expiration date

Inactive ingredients carboxer 934P, NF; FD&C blue #1 aluminum lake; hypromellose, USP; magnesium stearate, NF; microcrystalline cellulose, NF; sodium starch glycolate, NF



20 EXTENDED-RELEASE BI-LAYER TABLETS
 EXPECTORANT AND COUGH SUPPRESSANT
 extended-release bi-layer tablets
 60 mg dextromethorphan HBr
 1200 mg guaifenesin and
Mucinex^{DM}
NEW

Drug Facts (continued)

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.

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: one 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 seal on bottle printed "SEALED for YOUR PROTECTION" is broken or missing
- store at 20-25°C (68-77°F)
- see bottom of bottle for lot code and expiration date

Inactive ingredients carboron 934P, NF; FD&C blue #1 aluminum lake; hypromellose, USP; magnesium stearate, NF; microcrystalline cellulose, NF; sodium starch glycolate, NF

NEW

Mucinex^{DM}
 1200 mg guaifenesin and
 60 mg dextromethorphan HBr
 extended-release bi-layer tablets
EXPECTORANT AND COUGH SUPPRESSANT

Please visit our Web site:
www.mucinex.com

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 Fort Worth, Texas 76165
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 US Pat. 6,377,252 B1

NEW NDC 63824-037-20

Mucinex^{DM}
 1200 mg guaifenesin and
 60 mg dextromethorphan HBr
 extended-release bi-layer tablets
EXPECTORANT AND COUGH SUPPRESSANT



20 EXTENDED-RELEASE BI-LAYER TABLETS

3-63824-037-20-2

Drug Facts

Active ingredients (in each extended-release bi-layer tablet)	Purpose
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 a 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)

MUCINEX DM 1200/60 mg (20 count) CARTON

Title:
14 pt. Helvetica Bold
Italic, left justified

Headings:
8 pt. Helvetica Bold
Italic, left justified

Bullets:
5 pt. solid square
Zapf Dingbats

Subheadings:
6 pt. Helvetica Bold
left justified

Graphic leading
to next panel

Drug Facts

Active ingredients (in each extended-release bi-layer tablet)	Purpose
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 a 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)

Right justified

Drug Facts (continued)

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.

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: one 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 seal on bottle printed "SEALED FOR YOUR PROTECTION" is broken or missing
- store at 20-25°C (68-77°F)
- see bottom of bottle for lot code and expiration date

Inactive ingredients carbomer 934P, NF; FD&C blue #1 aluminum lake; hypromellose, USP; magnesium stearate, NF; microcrystalline cellulose, NF; sodium starch glycolate, NF

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Body text:
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**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Badrul Chowdhury
4/28/04 03:26:40 PM

Charles Ganley
4/29/04 03:57:18 PM