

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-282

APPROVED LABELING

2 Bi-layer Tablets

Mucinex 600 mg
NEW
Guaiifenesin Extended-Release Tablets
EXPECTORANT

Drug Facts

Active Ingredient (in each extended-release tablet) Purpose
Guaiifenesin 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

Warnings

Do not use ■ for children under 12 years of age

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)

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.

Drug Facts (continued)

Directions

- do not crush, chew, or break tablet
- take with a full glass of water
- this product can be administered without regard for the timing of meals
- adults and children 12 years of age and over: one or two tablets every 12 hours. Do not exceed 4 tablets in 24 hours.
- children under 12 years of age: do not use

Other information

- tamper evident: do not use if neckband is broken
- store between 20-25°C (68-77°F)
- see bottom of bottle for lot code and expiration date

Inactive ingredients carbomer 934P, NF, dyes, hydroxypropyl methylcellulose, USP, magnesium stearate, NF, microcrystalline cellulose, NF, sodium starch glycolate, NF

NDC 63824-008-82

Mucinex 600 mg
NEW
Guaiifenesin Extended-Release Tablets
EXPECTORANT



2 Bi-layer Tablets



3-63824-008-82-0

Mucinex 600 mg
Guaiifenesin Extended-Release Tablets
EXPECTORANT

Please visit our Web site:
www.adamslabs.com

PHYSICIAN SAMPLE-
NOT TO BE SOLD



Fort Worth, Texas 76155 022802
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NDC 63824-008-82
(41) 1712
Mucinex
Guaifenesin Extended-Release Tablets
EXPECTORANT
2 Bi-layer Tablets
SEE CARTON FOR COMPLETE INFORMATION

Directions

- do not crush, chew, or break tablet
- take with a full glass of water
- this product can be administered without regard for the timing of meals
- adults and children 12 years of age and over: one or two tablets every 12 hours. Do not exceed 4 tablets in 24 hours
- children under 12 years of age: do not use

PHYSICIAN
SAMPLE-
NOT TO BE SOLD

Adams

Fort Worth, Texas 76155

3100802

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3-63824-00882-0

NDC 63824-008-10

Mucinex^{600mg}
Guaifenesin Extended-Release Tablets

EXPECTORANT

3-6382400810-3

100 Bi-layer Tablets

Adams

LABORATORIES, Fort Worth, Texas 76155
3000810 022802

Drug Facts

Active Ingredient (in each extended-release tablet) Purpose
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

Warnings

Do not use ■ for children under 12 years of age

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)

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 ▶

Drug Facts (continued)

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 the timing of meals
- adults and children 12 years of age and over: one or two tablets every 12 hours. Do not exceed 4 tablets in 24 hours.
- children under 12 years of age: do not use

Other information

- tamper evident: do not use if neckband is broken
- store between 20-25°C (68-77°F)
- see bottom of bottle for lot code and expiration date

Inactive ingredients carbomer 934P, NF, dyes hydroxypropyl methylcellulose, USP, magnesium stearate, NF, microcrystalline cellulose, NF, sodium starch glycolate, NF

20 BI-LAYER TABLETS

EXPECTORANT
 Guaifenesin Extended-Release Tablets
Mucinex
 600 mg

Drug Facts

Active ingredient (in each extended-release tablet)	Purpose Expectorant
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

Warnings

Do not use ■ for children under 12 years of age

Ask a doctor before use if you have

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- cough accompanied by too much phlegm (mucus)

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.

NEW

Mucinex 600 mg
 Guaifenesin Extended-Release Tablets
EXPECTORANT

Drug Facts (continued)

Directions

- do not crush, chew or break tablet
- take with a full glass of water
- this product can be administered without regard for the timing of meals
- adults and children 12 years of age and over: one or two tablets every 12 hours. Do not exceed 4 tablets in 24 hours.
- children under 12 years of age: do not use

Other information

- tamper evident: do not use if neckband is broken
- store between 20-25°C (68-77°F)
- see bottom of bottle for lot code and expiration date

Inactive ingredients carbomer 934P, NF; dyes: hydroxypropyl methylcellulose, USP; magnesium stearate, NF; microcrystalline cellulose, NF; sodium starch glycolate, NF

NEW NDC 63824-008-20

Mucinex 600 mg
 Guaifenesin Extended-Release Tablets
EXPECTORANT

20 BI-LAYER TABLETS

NEW

Mucinex 600 mg
 Guaifenesin Extended-Release Tablets
EXPECTORANT

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 LABORATORIES
 Fort Worth, Texas 76155
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030002
 2000820

3-63824-008-20-2

NDC 63824-008-20
600 mg
Mucinex
 Guaifenesin Extended-Release Tablets
EXPECTORANT

20 Bi-layer Tablets

Adams
 LABORATORIES, Fort Worth, Texas 76155
 3000620 030002

Drug Facts

Active ingredient (in each extended-release tablet) Purpose
 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

Warnings

Do not use ■ for children under 12 years of age

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)

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

Drug Facts (continued)

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

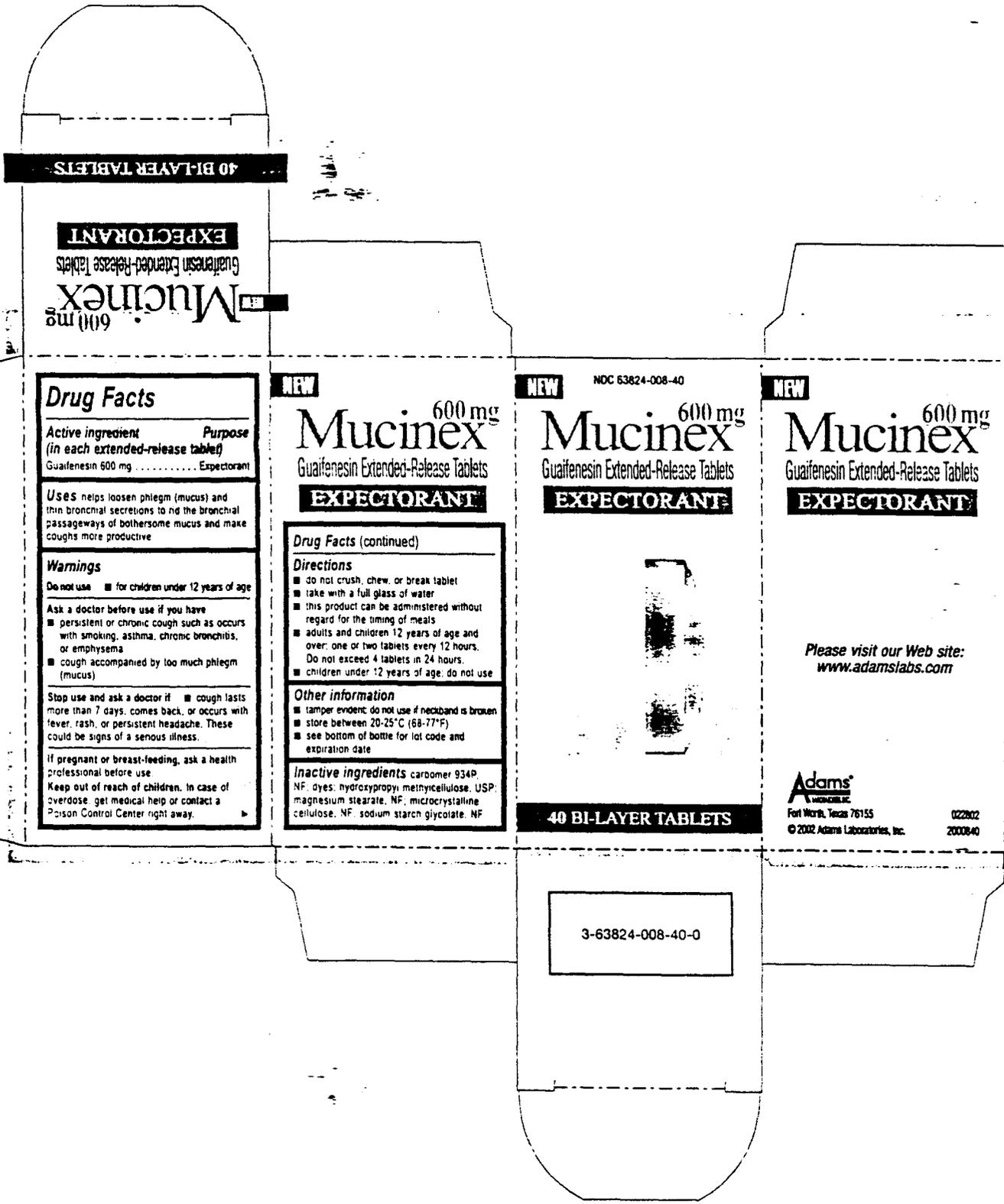
Directions

- do not crush, chew or break tablet
- take with a full glass of water
- this product can be administered without regard for the timing of meals
- adults and children 12 years of age and over: one or two tablets every 12 hours. Do not exceed 4 tablets in 24 hours.
- children under 12 years of age: do not use

Other information

- tamper evident: do not use if neckband is broken
- store between 20-25°C (68-77°F)
- see bottom of bottle for lot code and expiration date

Inactive ingredients carbomer 934P, NF, dyes, hydroxypropyl methylcellulose, USP, magnesium stearate, NF, microcrystalline cellulose, NF, sodium starch glycolate, NF



Drug Facts

Active ingredient (in each extended-release tablet)	Purpose
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

Warnings

Do not use ■ for children under 12 years of age

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)

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.

NEW

Mucinex 600 mg
Guaifenesin Extended-Release Tablets

EXPECTORANT

Drug Facts (continued)

Directions

- do not crush, chew, or break tablet
- take with a full glass of water
- this product can be administered without regard for the timing of meals
- adults and children 12 years of age and over: one or two tablets every 12 hours. Do not exceed 4 tablets in 24 hours.
- children under 12 years of age: do not use

Other information

- tamper evident: do not use if neckband is broken
- store between 20-25°C (68-77°F)
- see bottom of bottle for lot code and expiration date

Inactive ingredients carbomer 934P, NF; dyes: hydroxypropyl methylcellulose, USP; magnesium stearate, NF; microcrystalline cellulose, NF; sodium starch glycolate, NF

NEW NDC 63824-008-40

Mucinex 600 mg
Guaifenesin Extended-Release Tablets

EXPECTORANT

40 BI-LAYER TABLETS

NEW

Mucinex 600 mg
Guaifenesin Extended-Release Tablets

EXPECTORANT

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3-63824-008-40-0

NDC 63824-008-40

600 mg
Mucinex
Guaifenesin Extended-Release Tablets
EXPECTORANT

40 Bi-layer Tablets

Adams
Pharmaceutical, Fort Worth, Texas 76153
3400840 022802

Drug Facts

Active ingredient (in each extended-release tablet) Purpose
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

Warnings

Do not use for children under 12 years of age
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)
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

Drug Facts (continued)

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 the timing of meals
 adults and children 12 years of age and over one or two tablets every 12 hours. Do not exceed 4 tablets in 24 hours.
 children under 12 years of age do not use

Other information

tamper evident do not use if neckband is broken
 store between 20-25°C (68-77°F)
 see bottom of bottle for lot code and expiration date

Inactive ingredients carbomer 934P, NF, dyes, hydroxypropyl methylcellulose, USP, magnesium stearate, NF, microcrystalline cellulose, NF, sodium starch glycolate, NF

Drug Facts

Active ingredient (in each extended-release tablet) Purpose
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

Warnings

- Do not use
 - for children under 12 years of age
- 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)
- 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 the timing of meals
- adults and children 12 years of age and over: one or two tablets every 12 hours. Do not exceed 4 tablets in 24 hours.
- children under 12 years of age: do not use

Other information

- tamper evident, do not use if neckband is broken
- store between 20-25°C (68-77°F)
- see bottom of bottle for lot code and expiration date

Inactive ingredients carbomer 934P, NF, dyes, hydroxypropyl methylcellulose, USP, magnesium stearate, NF, microcrystalline cellulose, NF, sodium starch glycolate, NF

NDC 63824-008-50

Mucinex^{600mg}

Guafenesin Extended-Release Tablets

EXPECTORANT



500 Bi-layer Tablets

3-6382400850-9

022802
3000650

Adams
LABORATORIES Fort Worth, Texas 76155

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/s/

Badrul Chowdhury
7/12/02 03:44:27 PM

Linda Katz
7/12/02 03:49:12 PM
Linda M. Katz, M.D. signing for Charles J. Ganley, M.D.