APPLICATION NUMBER:
21-282

APPROVED LABELING
Mucinex 600 mg

Drug Facts

Active ingredient (in each extended-release tablet): Purpose
Guaifenesin 600 mg: Expectorant

Uses: Helps loosen phlegm (mucus) and make bronchial secretions easier to expectorate. It relieves blockage of bronchial passageways, making breathing easier and makes coughing 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)

Do not 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.
- you are pregnant or breastfeeding. 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 tablets.
- Take with a full glass of water.
- This product can be administered without regard for the amount of meals.
- Adults and children 12 years of age and over: one or two tablets every 4-6 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).
- Use bottom of bottle for lot code and expiration date.

Inactive ingredients:
- Carbomer 940,
- FD&C yellow No. 6,
- Hydroxypropyl methylcellulose USP,
- Magnesium stearate,
- Neat croscarmellose sodium,
- Sodium starch phosphate,
- Talc.

NDC 63824-008-82

Mucinex 600 mg

Guaifenesin Extended-Release Tablets

EXPECTORANT

Please visit our Web site: www.adamslabs.com

PHYSICIAN SAMPLE NOT TO BE SOLD

Adams Laboratories
Fort Worth, Texas 76135

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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 76115
310082 0072902

Mucinex
Expectorant
Cough, Cold, & Flu Relief Tablets
2 Bi-layer Tablets
SEE CARTON FOR COMPLETE INFORMATION

NDC 63024-008-02
6/11/1992
Mucinex
Guillenesis Extended-Release Tablets
EXpectorant

600 mg

3-6382400810-3

100 Bi-layer Tablets

Drug Facts
Active Ingredient (in each extended-release tablet): Purpose
Guillenesis 600 mg: Expectorant
Uses: Helps loosen phlegm (mucus) and thin bronchial secretions to
aid the natural passageway of breath. Some mucus and make coughs
more productive.

Warnings
Do not use
• for children under 12 years of age
• a doctor before using 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
• 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 to 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: carbonates, citrate, NF, dyes, hydroxypropyl
methylcellulose, USP, magnesium stearate, NF, microcrystalline
cellose, NF, sodium starch glycolate, NF.
Drug Facts
Active ingredient (in each extended-release tablet): Purpose
Guaifenesin 600 mg
Expectorant
Uses: Helps break up phlegm (mucus) and thin bronchial secretions.
In the bronchial passageways of the respiratory system, reduce coughs moreproductive.

Warnings
Do not use: in 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).
Do not 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
- Longer treating: do not use if packet is broken.
- Store between 20-25°C (68-77°F).
- See bottom of bottle for lot code and expiration date.

Inactive ingredients: Carbomer, FD&C, NF; dyes; hydroxypropyl methylcellulose, USP; magnesium stearate, NF; microcrystalline cellulose, NF; sodium starch glycolate, NF.
Drug Facts
Active ingredient
Guaifenesin 600 mg

Uses
Helps loosen phlegm (mucus) and thin bronchial secretions to make it easier for coughing.

Warnings
Do not use
- in children under 12 years of age.
- if you have
- persistent or chronic cough such as occurs with smoking, asthmatic, or emphysemic conditions.
- cough accompanied by too much phlegm (mucus)

Ask a doctor before use if you have
- persistent, non-productive cough for more than 7 days, comes back, or occurs with fever, rash, or persistent headache. These could be signs of a serious illness.

Other information
- Keep out of reach of children.
- Do not take if you are allergic to any of the ingredients.

Inactive ingredients
- Carbomer,
- D&C Yellow No. 10, D&C Red No. 30, FD&C Blue No. 1 Alum.,
- Macrogol 400,
- Magnesium stearate,
- Sodium benzoate,
- Sorbitol solution,
- Sucrose,
- Talc,
- Tartaric acid,
- Tetrahydropropylammonium chloride,
- Water.

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.

To Report SUSPECTED ADVERSE REACTIONS, contact your healthcare provider or call the FDA at 1-800-FDA-1088.

Please visit our Web site: www.adamslabs.com
Drug Facts

Active ingredient (in each extended-release tablet): Purpose
Guaifenesin 600 mg . Expectorant

Uses: Helps loosen phlegm (mucus) and lessens bronchial irritation to relieve cough accompanied by a buildup of mucus in the chest.

Warnings
Do not use: ■ in children under 12 years of age
Ask a doctor before use: if you have: ■ persistent or chronic cough, especially with hard breathing, chest pain, or nausea
■ cough accompanied by too much phlegm (mucus)
Stop use and ask a doctor if: ■ cough lasts more than 7 days, comes back, or is accompanied with fever, rash, or persistent headache
■ these could be signs of a serious illness
■ 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 4 hours. Do not exceed 8 tablets in 24 hours.
■ children under 12 years of age: do not use.

Other information
■ longer duration of use may be habit forming
■ store between 20-25°C (68-77°F)
■ see bottom of bottle for lot code and expiration date

Inactive ingredients: carbon black, FD&C blue No. 2, hydroxypropyl methylcellulose, USP, magnesium stearate NF, microcrystalline cellulose NF, sodium starch glycolate NF.
**Drug Facts**

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

Guaiifenesin 600 mg 

**Uses**

- Helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive

**Warnings**

- Do not use: ■ for children under 12 years of age
- Ask a doctor before use if you have:
  - Chronic bronchitis, 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**

- Take with a full glass of water
- Do not crush, chew, or break tablet
- Do not exceed 4 tablets in 24 hours

**Other Information**

- Store between 20°-25°C (68°-77°F)
- See bottom of bottle for lot code and expiration date

**Inactive ingredients**

- Carmeron NC, NF, dyestuffs
- Hydroxypropyl methylcellulose, USP, magnesium stearate, NF
- Microcrystalline cellulose, NF
- Sodium starch glycolate, NF

**NDC 63824-008-50**

**Mucinex**

600 mg

Guaiifenesin Extended-Release Tablets

**EXPECTORANT**

500 Bi-layer Tablets
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
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.