

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
21-585

APPROVED LABELING

All pages are accounted for in this document.
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NDC 63824-057-82

Mucinex^D

600 mg guaifenesin and
60 mg pseudoephedrine HCl per tablet

**EXPECTORANT AND
NASAL DECONGESTANT**

2 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: two tablets every 12 hours; not more than 8 tablets in 24 hours
- children under 12 years of age: do not use

Contains FDAC Yellow Dye #6

PHYSICIAN SAMPLE
NOT TO BE SOLD

Adams[®]
LABORATORIES, INC.
Fort Worth, Texas 76156
US Pat. 6,377,252 B1
3105702 102003


3-63824-05782-8

4 1/4"

15/16"

NDC 63824-057-20

Mucinex-D
600 mg guaifenesin and
60 mg pseudoephedrine HCl per tablet
**EXPECTORANT AND
NASAL DECONGESTANT**



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

See carton for complete Drug Facts.

US Pat. 6,372,252 B1

102003
3005720

Contains FD&C Yellow Dye #6

Please visit our Web site:
www.mucinex.com

Adams
LABORATORIES, INC.
Fort Worth, Texas 76155
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5 1/4"

2"

NDC 63824-057-40

Mucinex[®]D
600 mg guaifenesin and
60 mg pseudoephedrine HCl per tablet

**EXPECTORANT AND
NASAL DECONGESTANT**



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

See carton for complete Drug Facts.

102003
US Pat. 6,372,252 B1 3005740

Contains FD&C Yellow Dye #6

Please visit our Web site:
www.mucinex.com

Adams[®]
LABORATORIES, INC.
Fort Worth, Texas 76155
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5 1/4"

2"

NDC 63824-034-82

Mucinex^D

1200 mg guaifenesin and
120 mg pseudoephedrine HCl per tablet

**EXPECTORANT AND
NASAL DECONGESTANT**

2 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: 1 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. 6,372,282 B1
3103402 102003


3-63824-03482-9

4 1/4"

15/16"

NDC 63824-034-01

Mucinex^D
1200 mg guaifenesin and
120 mg pseudoephedrine HCl per tablet
**EXPECTORANT AND
NASAL DECONGESTANT**



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

See carton for complete Drug Facts.

US Pat. 6,372,252 B1

102003
3003401

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5 1/4"

2"

NDC 63824-034-20

Mucinex^D
1200 mg guaifenesin and
120 mg pseudoephedrine HCl per tablet
**EXPECTORANT AND
NASAL DECONGESTANT**



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

*Please visit our Web site:
www.mucinex.com*

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Fort Worth, Texas 76155
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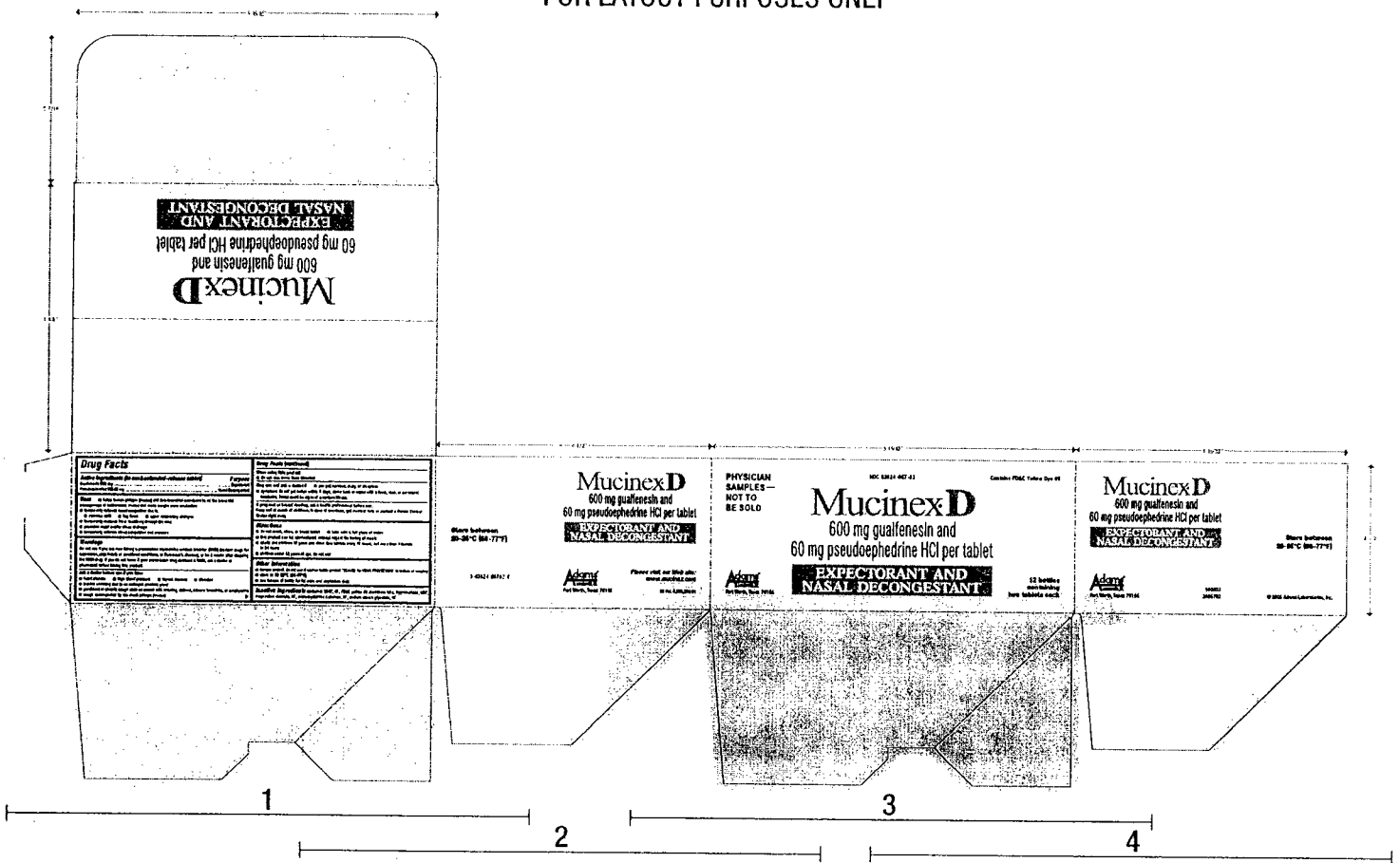
See carton for complete Drug Facts.

102003
US Pat. 6,372,252 B1 3003420

5 1/4"

2"

FOR LAYOUT PURPOSES ONLY



MUCINEX D 600/60 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:
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left justified

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Drug Facts

Active ingredients (in each extended-release tablet)

Guafenesin 600 mg
Pseudoephedrine HCl 60 mg

Purpose

Expectorant
Nasal Decongestant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily relieves nasal congestion due to:
 - common cold
 - hay fever
 - upper respiratory allergies
- temporarily restores faster breathing through the nose
- promotes nasal and/or sinus drainage
- temporarily relieves sinus congestion and pressure

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 a MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- 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

- you get nervous, dizzy, or sleepless
- symptoms do not get better within 7 days, come back or occur with a 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: 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 carboxymethylcellulose 3346, NF; FD&C yellow #6 aluminum lake; hypromellose, USP; magnesium stearate, NF; microcrystalline cellulose, NF; sodium starch glycolate, NF

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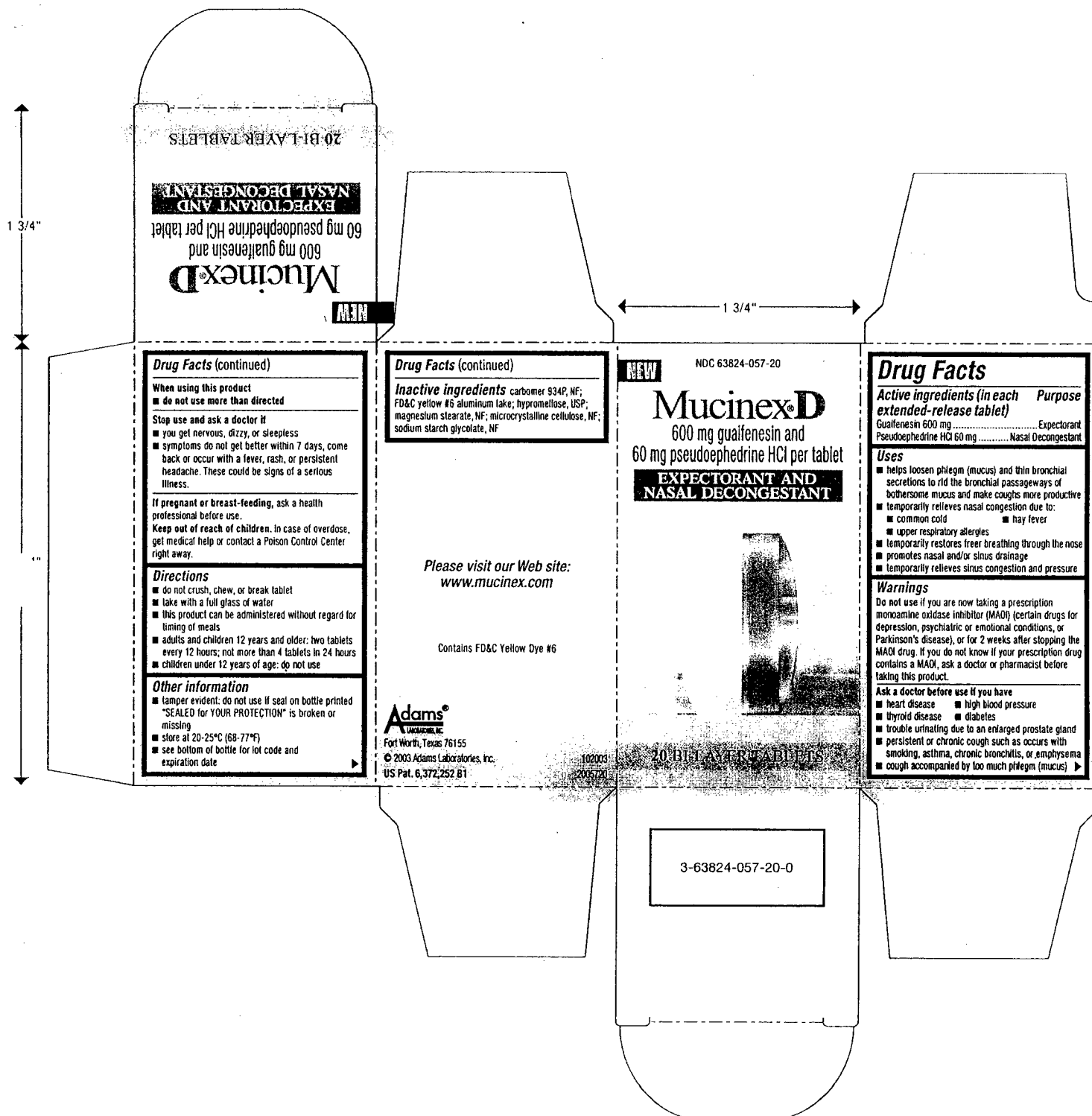
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MUCINEX D 600/60 mg (20 count) CARTON

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Italic, left justified

Bullets:
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Zapf Dingbats

Subheadings:
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Drug Facts

Active ingredients (in each extended-release tablet)	Purpose
Guaifenesin 600 mg	Expectorant
Pseudoephedrine HCl 60 mg	Nasal Decongestant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily relieves nasal congestion due to:
 - common cold
 - hay fever
- upper respiratory allergies
- temporarily restores easier breathing through the nose
- promotes nasal and/or sinus drainage
- temporarily relieves sinus congestion and pressure

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 a MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- 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

- you get nervous, dizzy, or sleepless
- symptoms do not get better within 7 days, come back or occur with a 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: 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

Drug Facts (continued)

Inactive ingredients: carbomer 934P, NF; FD&C yellow #6 aluminum lake; hypromellose, USP; magnesium stearate, NF; microcrystalline cellulose, NF; sodium starch glycolate, NF.

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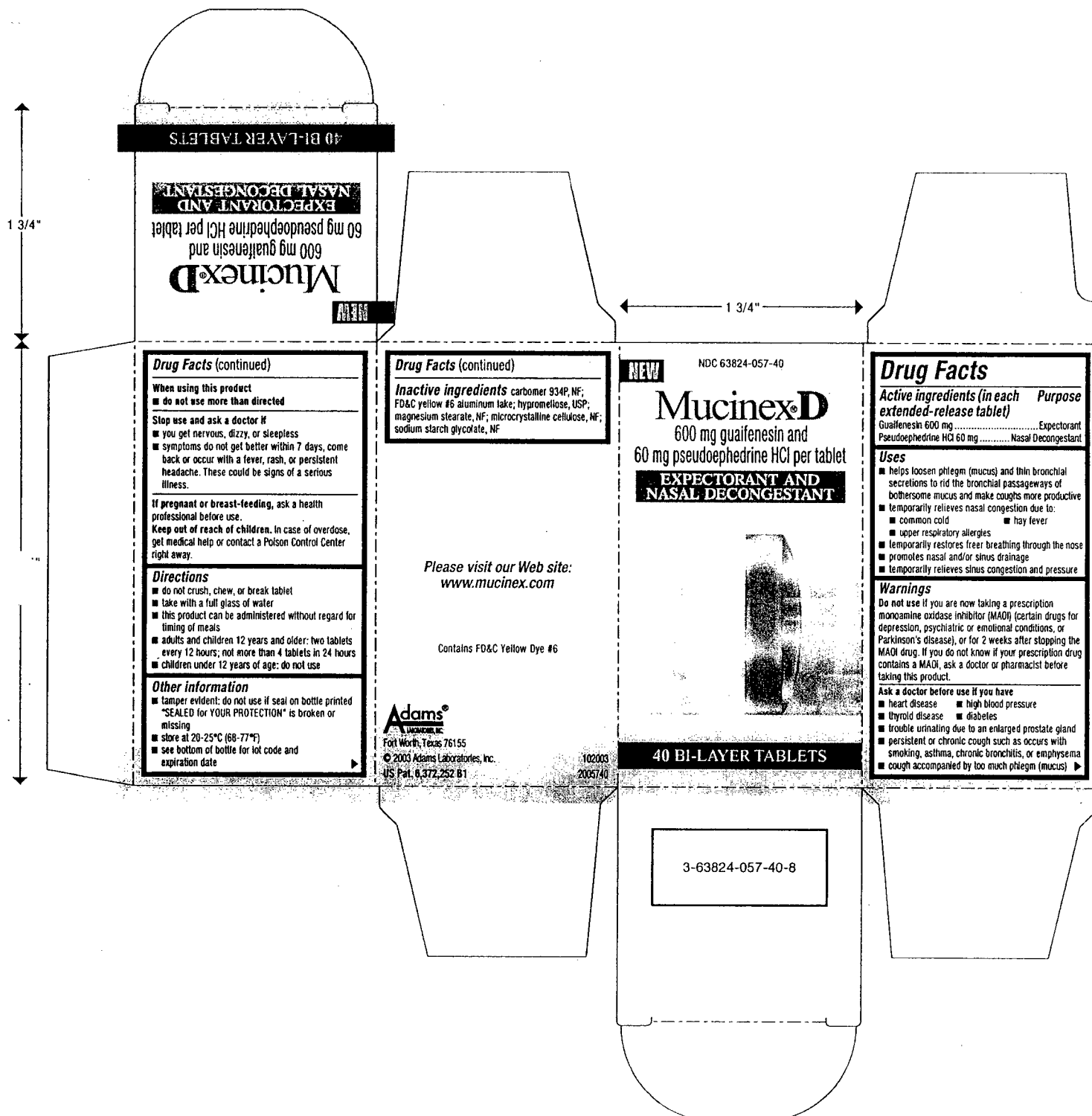
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MUCINEX D 600/60 mg (40 count) CARTON

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Headings:
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Italic, left justified

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Zapf Dingbats

Subheadings:
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Body text:
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Drug Facts

Active ingredients (in each extended-release tablet)

Active ingredients (in each extended-release tablet)	Purpose
Guaifenesin 600 mg	Expectorant
Pseudoephedrine HCl 60 mg	Nasal Decongestant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily relieves nasal congestion due to:
 - common cold
 - hay fever
- upper respiratory allergies
- temporarily restores freer breathing through the nose
- promotes nasal and/or sinus drainage
- temporarily relieves sinus congestion and pressure

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 a MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have:

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- 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

- you get nervous, dizzy, or sleepless
- symptoms do not get better within 7 days, come back or occur with a 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

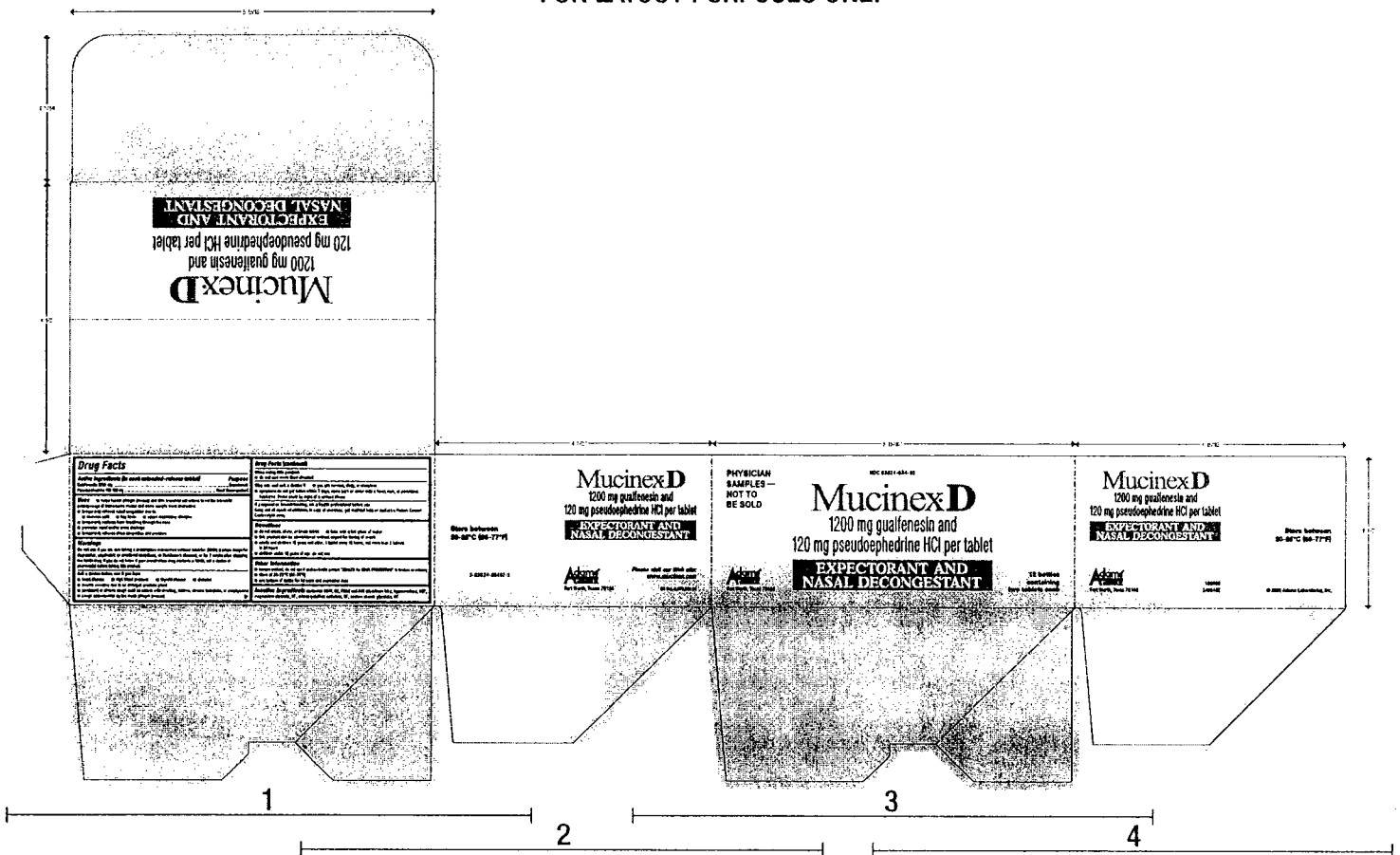
- do not crush, chew, or break tablet
- take with a full glass of water
- this product can be administered without regard for timing of meals
- adults and children 12 years and older: two tablets every 12 hours; not more than 4 tablets in 24 hours
- children under 12 years of age: do not use

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

Drug Facts (continued)

Inactive ingredients carboner 934P, NF; FD&C yellow 46 aluminum lake; hypromellose, USP; magnesium stearate, NF; microcrystalline cellulose, NF; sodium starch glycolate, NF



MUCINEX D 1200/120 mg SAMPLE TRAY

Title:
14 pt. Helvetica Bold
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Italic, left justified

Bullets:
5 pt. solid square
Zapf Dingbats

Subheadings:
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Drug Facts	
Active ingredients (in each extended-release tablet)	Purpose
Guafenesin 1200 mg.....	Expectorant
Pseudoephedrine HCl 120 mg.....	Nasal decongestant
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 nasal congestion due to: <ul style="list-style-type: none"> ■ common cold ■ hay fever ■ upper respiratory allergies ■ temporarily restores freer breathing through the nose ■ promotes nasal and/or sinus drainage ■ temporarily relieves sinus congestion and pressure 	
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 a MAOI, ask a doctor or pharmacist before taking this product.	
<ul style="list-style-type: none"> ■ Ask a doctor before use if you have <ul style="list-style-type: none"> ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes ■ trouble urinating due to an enlarged prostate gland ■ 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	
<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"> ■ you get nervous, dizzy, or sleepless
<ul style="list-style-type: none"> ■ symptoms do not get better within 7 days, come back or occur with a fever, rash, or persistent headache. These could be signs of a serious illness. 	
Directions	
<ul style="list-style-type: none"> ■ 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. 	
Other information	
<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: 1 tablet every 12 hours; not more than 2 tablets in 24 hours ■ children under 12 years of age: do not use 	
Inactive ingredients	carbowax 934P, NF; FD&C red #40 aluminum lake; hypromellose, USP; magnesium stearate, NF; microcrystalline cellulose, NF; sodium starch glycolate, NF

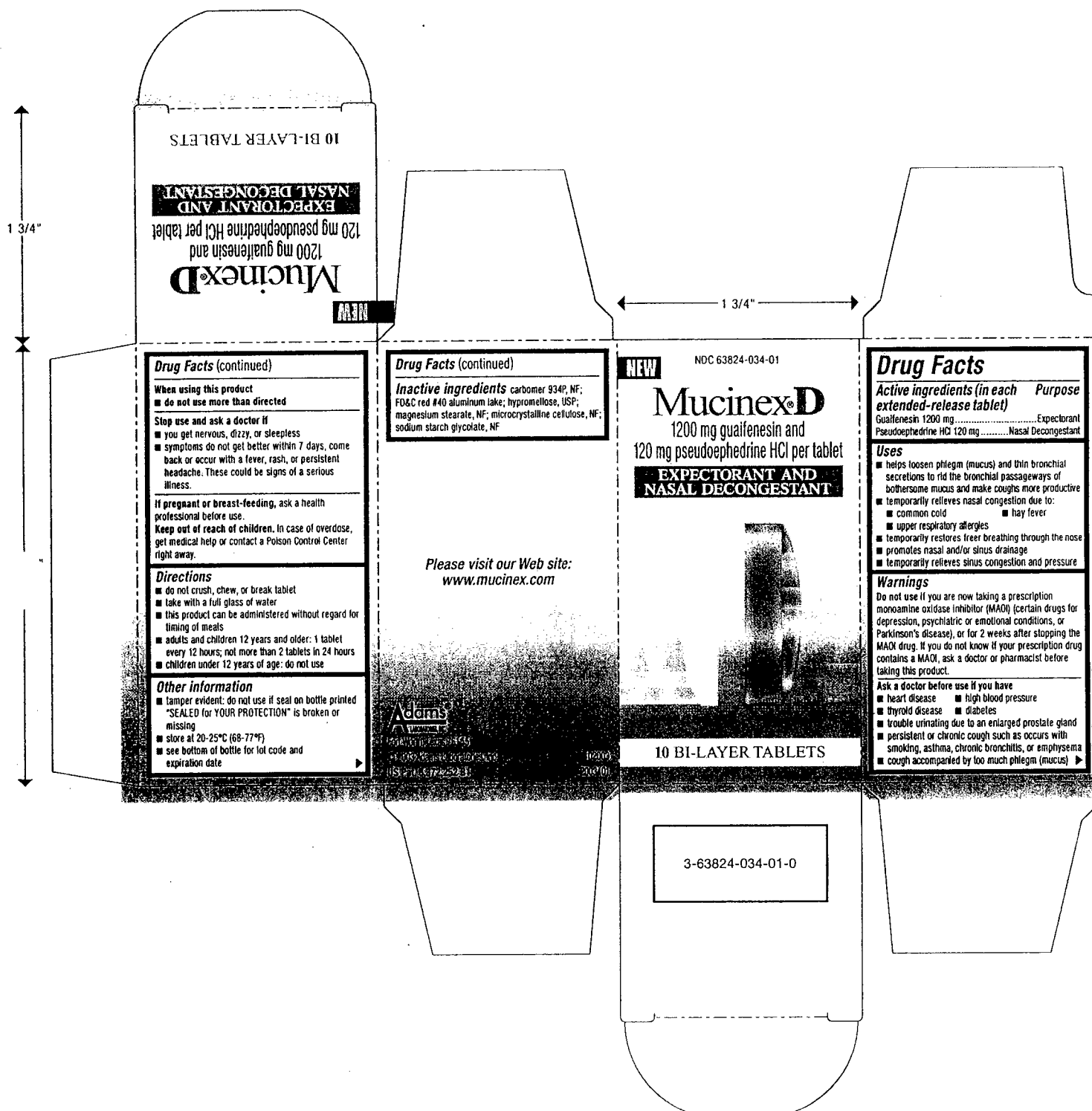
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Body text:
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with 6.5 pt. leading,
left justified

2.5 pt. box barline



MUCINEX D 1200/120 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

Right justified

Title for continued panel:
8 pt. Helvetica Bold Italic

8 pt. Helvetica Regular

2.5 pt. barline

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

0.5 pt. hairline

2.5 pt. box barline

Drug Facts	
Active ingredients (in each extended-release tablet)	Purpose
Quafenesin 1200 mg	Expectorant
Pseudoephedrine HCl 120 mg	Nasal Decongestant
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 nasal congestion due to: <ul style="list-style-type: none"> ■ common cold ■ hay fever ■ upper respiratory allergies ■ temporarily restores freer breathing through the nose ■ promotes nasal and/or sinus drainage ■ temporarily relieves sinus congestion and pressure 	
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 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"> ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes ■ trouble urinating due to an enlarged prostate gland ■ persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema ■ cough accompanied by too much phlegm (mucus) 	
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: 1 tablet every 12 hours; not more than 2 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 	

Drug Facts (continued)

When using this product

- do not use more than directed

Stop use and ask a doctor if

- you get nervous, dizzy, or sleepless
- symptoms do not get better within 7 days, come back or occur with a 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

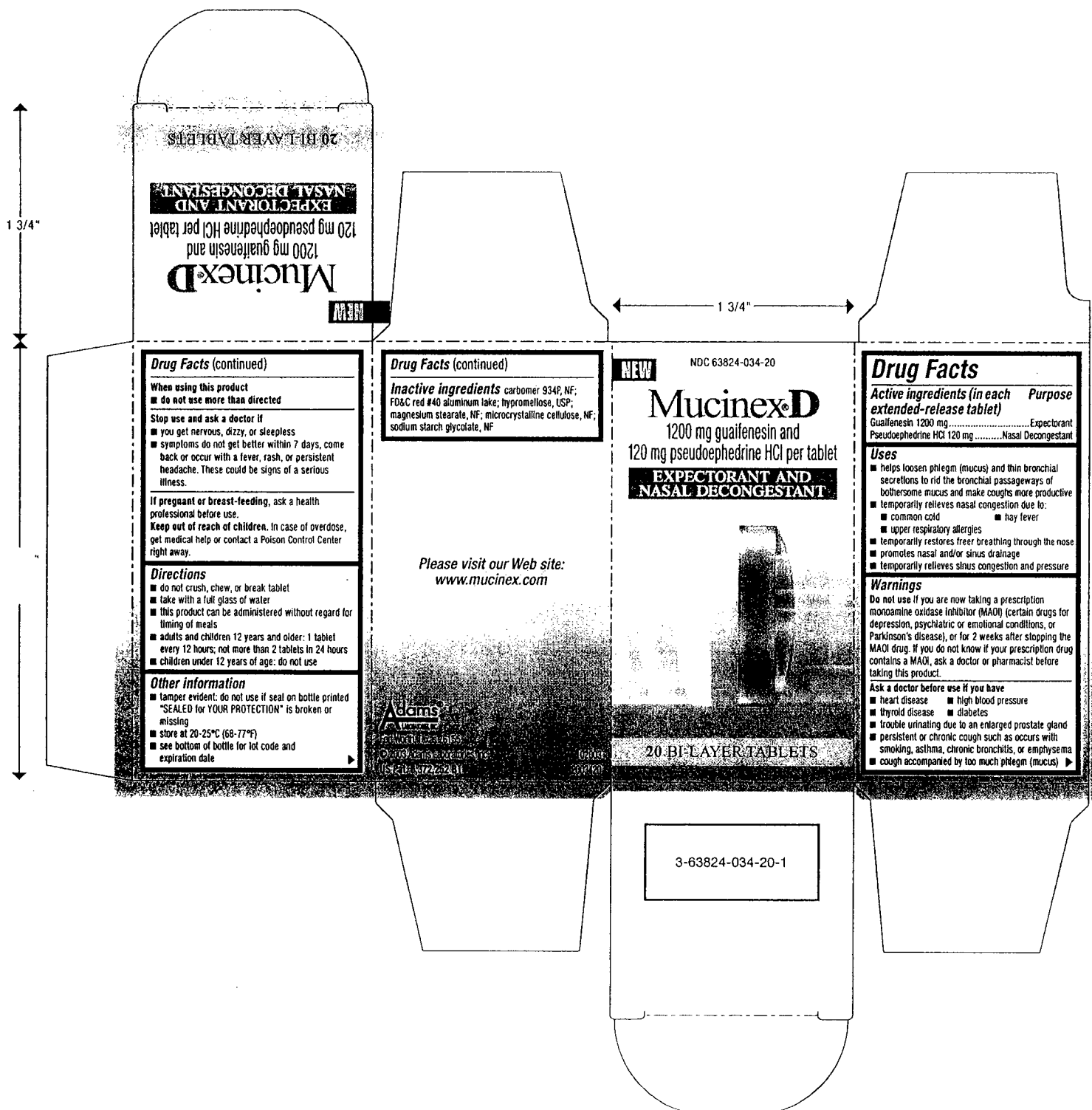
- do not crush, chew, or break tablet
- take with a full glass of water
- this product can be administered without regard for timing of meals
- adults and children 12 years and older: 1 tablet every 12 hours; not more than 2 tablets in 24 hours
- children under 12 years of age: do not use

Other Information

- tamper evident: do not use if 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

Drug Facts (continued)

Inactive ingredients carbomer 934P, NF; FD&C red #40 aluminum lake, hypromellose, USP; magnesium stearate, NF; microcrystalline cellulose, NF; sodium starch glycolate, NF



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/s/

Badrul Chowdhury
6/22/04 01:09:05 PM

Curtis Rosebraugh
6/22/04 02:38:36 PM