GUAIFENESIN- guaifenesin tablet, extended release
Amneal Pharmaceuticals LLC

Guaifenesin Extended-Release Tablets

Active ingredient(s)

Active ingredient (in each extended-release tablet)

Guaifenesin 600 mg

Active ingredient (in each extended-release tablet)

Guaifenesin 1200 mg

Purpose

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.

Pregnancy/Breastfeeding

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 (1-800-222-1222).

Directions

600 mg
- do not crush, chew, or break extended-release 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: 1 or 2 extended-release tablets every 12 hours. Do not exceed 4 extended-release tablets in 24 hours.
- children under 12 years of age: do not use

1200 mg
- do not crush, chew, or break extended-release 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: 1 extended-release tablet every 12 hours; not more than 2 extended-release tablets in 24 hours.
- children under 12 years of age: do not use

Other information
- **Tamper evident: Do not use if printed foil under cap is broken or missing.**

Storage
- store between 20° to 25°C (68° to 77°F)

Inactive ingredients

carbomer, colloidal silicon dioxide, FD&C blue #1 aluminum lake, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone and talc

Questions

1-877-835-5472 You may also report side effects to this phone number.

Distributed by:
Amneal Pharmaceuticals LLC
Bridgewater, NJ 08807

Rev. 10-2024-01

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Guaifenesin Extended-Release Tablet 600 mg

Distributed by: Amneal Pharm.
Bridgewater, NJ 08807

Guaifenesin Extended-Release Tablet 600 mg

Distributed by: Amneal Pharm.
Bridgewater, NJ 08807

Guaifenesin Extended-Release Tablet 600 mg

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Guaifenesin Extended-Release Tablet 600 mg

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Bridgewater, NJ 08807

PUSH TABLET THROUGH FOIL

Rev. 11-2017-00

Non-Varnish Area

Lot No:
Exp. Date:

Guaifenesin Extended-Release Tablet 600 mg

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Bridgewater, NJ 08807

Guaifenesin Extended-Release Tablet 600 mg

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†Compare to the active ingredient of Mucinex®

NDC 65162-**036**-02

Guaifenesin Extended-Release Tablets

600 mg

EXPECTORANT

12 Hour

✓ Relieves Chest Congestion

✓ Thins And Loosens Mucus

AN036

Actual size

20 Extended-Release Tablets

amneal

Guaifenesin Extended-Release Tablets 600 mg RELIEVES CHEST CONGESTION

N 3 65162 03602 2

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 (1-800-222-1222).

Drug Facts (continued)

Directions

- do not crush, chew, or break extended-release 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: 1 or 2 extended-release tablets every 12 hours. Do not exceed 4 extended-release tablets in 24 hours
- children under 12 years of age: do not use

Other information

- **Tamper evident: Do not use if carton is open or if printed seal with product name on blister is broken or missing.**
- store between 20° to 25°C (68° to 77°F)

Inactive ingredients carbomer, colloidal silicon dioxide, FD&C blue #1 aluminum lake, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone and talc

Questions? **1-877-835-5472**
You may also report side effects to this phone number.

Distributed by:
Amneal Pharmaceuticals LLC
Bridgewater, NJ 08807

Rev. 10-2024-01

Keep the carton. It contains important information.
See bottom panel for expiration date.

†Mucinex® is a registered trademark of Reckitt Benckiser LLC.

Lot No:

Exp. Date:

Guaifenesin Extended-Release Tablets 600 mg RELIEVES CHEST CONGESTION FOR DAY OR NIGHT

†Compare to the active ingredient of Mucinex®

NDC 65162-**036**-03

Guaifenesin Extended-Release Tablets

600 mg

EXPECTORANT

AN036

30 Extended-Release Tablets

amneal

Directions

- **do not crush, chew, or break extended-release 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: 1 or 2 extended-release tablets every 12 hours. Do not exceed 4 extended-release tablets in 24 hours**
- **children under 12 years of age: do not use**

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Bridgewater, NJ 08807 Rev. 10-2024-01

Keep the carton. It contains important information.
See side panel for expiration date.

†Mucinex® is a registered trademark of Reckitt Benckiser LLC.

N 3 65162 03603 9

0.75" x 1.5"
Non-Varnish Area for
Lot No. and Exp. Date
and Serialization

Guaifenesin Extended-Release Tablets

600 mg

EXPECTORANT

†Compare to the active ingredient of Mucinex®

NDC 65162-**036**-03

Guaifenesin Extended-Release Tablets

600 mg

EXPECTORANT

12 Hour

✓ Relieves Chest Congestion

✓ Thins And Loosens Mucus

Actual size

30 Extended-Release Tablets

amneal

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.

Drug Facts (continued)

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 (1-800-222-1222).

Directions

- do not crush, chew, or break extended-release 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: 1 or 2 extended-release tablets every 12 hours. Do not exceed 4 extended-release tablets in 24 hours
- children under 12 years of age: do not use

Other information

- **Tamper evident: Do not use if printed foil under cap is broken or missing.**
- store between 20° to 25°C (68° to 77°F)

Drug Facts (continued)

Inactive ingredients carbomer, colloidal silicon dioxide, FD&C blue #1 aluminum lake, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone and talc

Questions? **1-877-835-5472**
You may also report side effects to this phone number.

Distributed by:
Amneal Pharmaceuticals LLC
Bridgewater, NJ 08807 Rev. 10-2024-01

Keep the carton. It contains important information.
See bottom panel for expiration date.

†Mucinex® is a registered trademark of Reckitt Benckiser LLC.

N 3 65162 03603 9

1.5" x 1.5"
Non-Varnish Area for
Lot No. and Exp. Date
and Serialization

E68

01 26115

Maximum Strength Guaifenesin Extended-Release Tablet 1200 mg

Distributed by: Amneal Pharm.
Bridgewater, NJ 08807

Maximum Strength Guaifenesin Extended-Release Tablet 1200 mg

Distributed by: Amneal Pharm.
Bridgewater, NJ 08807

Maximum Strength Guaifenesin Extended-Release Tablet 1200 mg

Distributed by: Amneal Pharm.
Bridgewater, NJ 08807

Maximum Strength Guaifenesin Extended-Release Tablet 1200 mg

Distributed by: Amneal Pharm.
Bridgewater, NJ 08807

Maximum Strength Guaifenesin Extended-Release Tablet 1200 mg

Distributed by: Amneal Pharm.
Bridgewater, NJ 08807

Maximum Strength Guaifenesin Extended-Release Tablet 1200 mg

Distributed by: Amneal Pharm.
Bridgewater, NJ 08807

Maximum Strength Guaifenesin Extended-Release Tablet 1200 mg

PUSH TABLET THROUGH FOIL

Rev. 12-2017-00

Non-Varnish Area

Lot No:
Exp. Date:

Maximum Strength Guaifenesin Extended-Release Tablet 1200 mg

Distributed by: Amneal Pharm.
Bridgewater, NJ 08807

Maximum Strength Guaifenesin Extended-Release Tablet 1200 mg

Distributed by: Amneal Pharm.
Bridgewater, NJ 08807

Maximum Strength Guaifenesin Extended-Release Tablet 1200 mg

Distributed by: Amneal Pharm.
Bridgewater, NJ 08807

Maximum Strength Guaifenesin Extended-Release Tablet 1200 mg

Distributed by: Amneal Pharm.
Bridgewater, NJ 08807

Maximum Strength Guaifenesin Extended-Release Tablet 1200 mg

Distributed by: Amneal Pharm.
Bridgewater, NJ 08807

Maximum Strength Guaifenesin Extended-Release Tablet 1200 mg

Distributed by: Amneal Pharm.
Bridgewater, NJ 08807

Maximum Strength Guaifenesin Extended-Release Tablet 1200 mg

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Distributed by: Amneal Pharm.
Bridgewater, NJ 08807

MAXIMUM STRENGTH

†Compare to the active ingredient of Mucinex®

NDC 65162-**037**-28

Guaifenesin Extended-Release Tablets

1200 mg

EXPECTORANT

12 Hour

✓ Relieves Chest Congestion

✓ Thins And Loosens Mucus

Actual size

28 Extended-Release Tablets

amneal

Guaifenesin Extended-Release Tablets 1200 mg RELIEVES CHEST CONGESTION

N 3 65162 03728 9

Drug Facts

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

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 (1-800-222-1222).

Drug Facts (continued)

Directions

- do not crush, chew, or break extended-release 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: 1 extended-release tablet every 12 hours; not more than 2 extended-release tablets in 24 hours
- children under 12 years of age: do not use

Other information

- **Tamper evident: Do not use if carton is open or if printed seal with product name on blister is broken or missing.**
- store between 20° to 25°C (68° to 77°F)

Inactive ingredients carbomer, colloidal silicon dioxide, FD&C blue #1 aluminum lake, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone and talc

Questions? **1-877-835-5472**
You may also report side effects to this phone number.

Distributed by:
Amneal Pharmaceuticals LLC
Bridgewater, NJ 08807

Rev. 10-2024-01

Keep the carton. It contains important information.
See bottom panel for expiration date.

†Mucinex® is a registered trademark of Reckitt Benckiser LLC.

Lot No:

Exp. Date:

Guaifenesin Extended-Release Tablets 1200 mg RELIEVES CHEST CONGESTION FOR DAY OR NIGHT

MAXIMUM STRENGTH

†Compare to the active ingredient of Mucinex®

NDC 65162-**037**-03

Guaifenesin Extended-Release Tablets

1200 mg

EXPECTORANT

30 Extended-Release Tablets

amneal

Directions

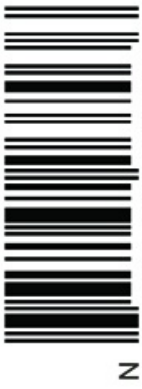
- **do not crush, chew, or break extended-release tablet**
- **take with a full glass of water**
- **this product can be administered without regard for the timing of meals**
- **adults and children 12 years of age and over: 1 extended-release tablet every 12 hours; not more than 2 extended-release tablets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

Distributed by: **Amneal Pharmaceuticals LLC**
Bridgewater, NJ 08807

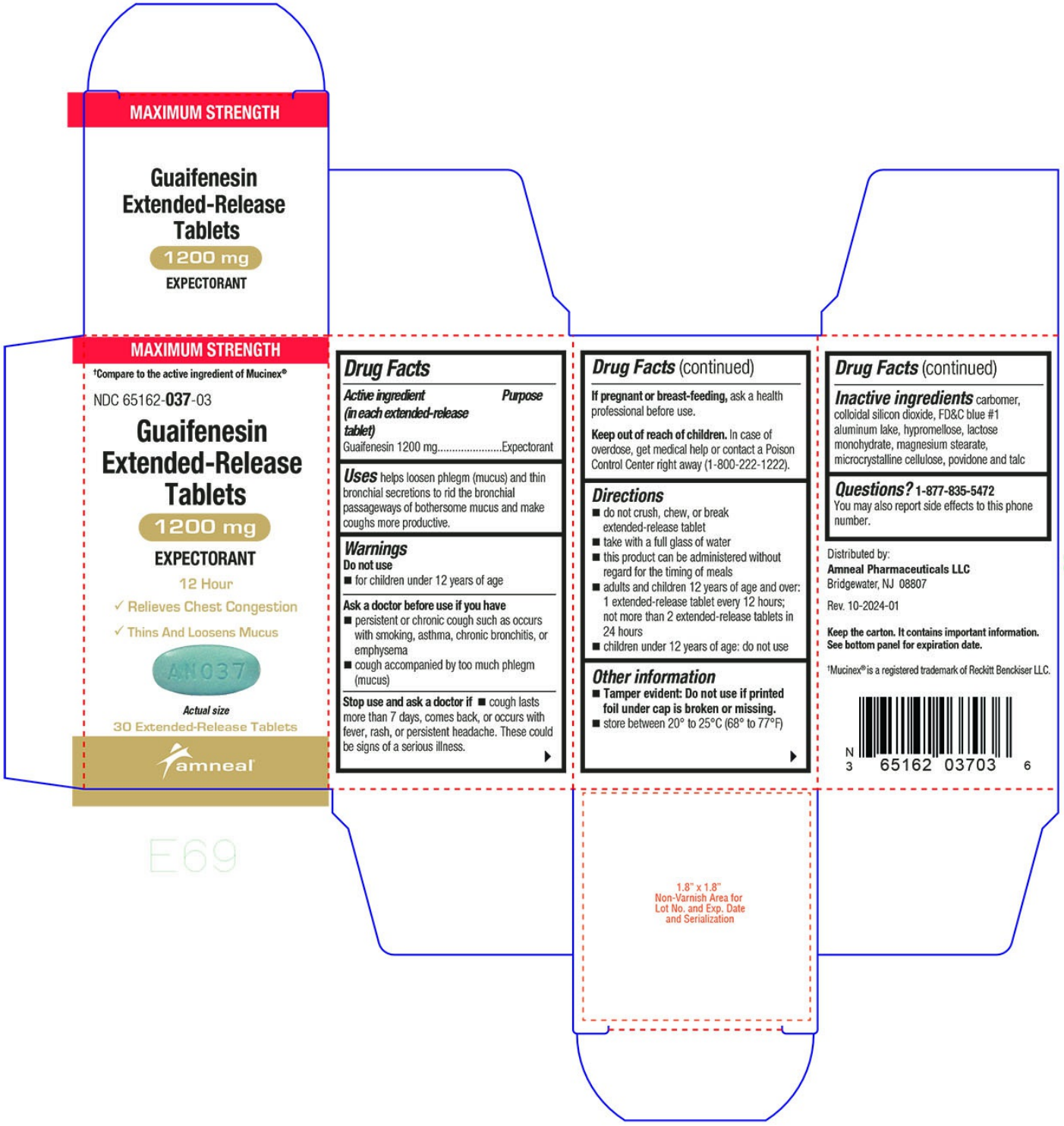
Rev. 10-2024-01

Keep the carton. It contains important information.
See side panel for expiration date.

†Mucinex® is a registered trademark of Reckitt Benckiser LLC.



0.75" x 2"
Non-Varnish Area for
Lot No. and Exp. Date
and Serialization



GUAIFENESIN

guaifenesin tablet, extended release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:65162-036
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	600 mg

Inactive Ingredients

Ingredient Name	Strength
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	blue (light blue)	**Score**	no score
Shape	OVAL	**Size**	16mm
Flavor		**Imprint Code**	AN036
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65162-036-02	2 in 1 CARTON	07/27/2018	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:65162-036-03	1 in 1 CARTON	07/27/2018	
2		30 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:65162-036-06	1 in 1 CARTON	07/27/2018	
3		60 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207342	07/27/2018	

GUAIFENESIN

guaifenesin tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:65162-037
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	1200 mg

Inactive Ingredients

Ingredient Name	Strength
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	blue (light blue)	**Score**	no score
Shape	OVAL	**Size**	22mm
Flavor		**Imprint Code**	AN037
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65162-037-28	2 in 1 CARTON	07/27/2018	
1		14 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:65162-037-03	1 in 1 CARTON	07/27/2018	
2		30 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:65162-037-06	1 in 1 CARTON	07/27/2018	
3		60 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207342	07/27/2018	

Labeler - Amneal Pharmaceuticals LLC (123797875)

Establishment

Name	Address	ID/FEI	Business Operations
Amneal Pharmaceuticals of New York, LLC		123797875	analysis(65162-036, 65162-037) , label(65162-036, 65162-037) , manufacture(65162-036, 65162-037) , pack(65162-036, 65162-037)

Revised: 10/2024 Amneal Pharmaceuticals LLC