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

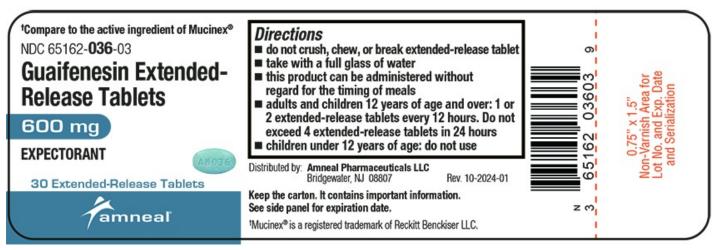
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Guaifenesin Extended-Guaifenesin Extended-Release Tablet 600 mg Release Tablet 600 mg Distributed by: Amneal Pharm. Distributed by: Amneal Pharm. Bridgewater, NJ 08807 Bridgewater, NJ 08807 Guaifenesin Extended-Guaifenesin Extended-Release Tablet 600 mg Release Tablet 600 mg Distributed by: Amneal Pharm. Distributed by: Amneal Pharm. Bridgewater, NJ 08807 Bridgewater, NJ 08807 **E** HROUGH Non-Varnish Area Rev. 11-2017-00 Guaifenesin Extended-Guaifenesin Extended-Release Tablet 600 mg Release Tablet 600 mg PUSH TABLET Distributed by: Amneal Pharm. Distributed by: Amneal Pharm. Bridgewater, NJ 08807 Bridgewater, NJ 08807 Lot No: Exp. Date: Guaifenesin Extended-Guaifenesin Extended-Release Tablet 600 mg Release Tablet 600 mg Distributed by: Amneal Pharm. Distributed by: Amneal Pharm. Bridgewater, NJ 08807 Bridgewater, NJ 08807

Guaifenesin Extended-Release Tablet 600 mg

Guaifenesin Extended-Release Tablet 600 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

Distributed by: Amneal Pharm. Bridgewater, NJ 08807

Maximum Strength Guaifenesin Extended-Release Tablet 1200 mg

<u>5</u> **ISH TABLET THROUGH** Δ

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

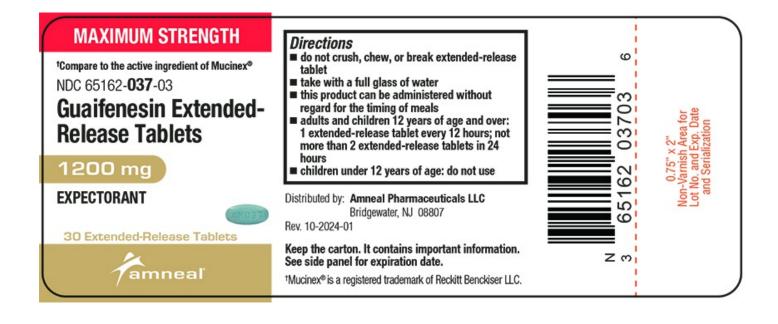
Von-Varnish Area Rev. 12-2017-00

Lot No: Exp. Date:

Distributed by: Amneal Pharm. Bridgewater, NJ 08807

Distributed by: Amneal Pharm. Bridgewater, NJ 08807







GUAIFENESIN guaifenesin tablet, extended	release		
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65162-036
Route of Administration	ORAL		

			e Moiety			_			
Ingredient Name GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)					Basis of Strength		Strength		
σι	AIFENESIN (UN	II: 495W/451	/Q) (GUAIFENES II	N - UNII:495W	7451VQ)	GUAI	FENESIN		600 mg
In	active Ingre	edients							
			Ingredie	nt Name				S	trength
CA		DLYMER TYP	E A (UNII: 71DD5	V995L)					
SI	ICON DIOXIDE	(UNII: ETJ7Z6	SXBU4)						
	&C BLUE NO.								
	PROMELLOSES								
			II: EWQ57Q8I5X)						
			.INE (UNII: OP1R3	32D61U)					
	VIDONE (UNII: F			5280107					
	LC (UNII: 7SEV7)								
Pı	oduct Char	acteristic	S						
	lor		light blue)		Score			no sco	ore
	аре	OVAL			Size			16mm	
	avor		Imprint			t Code AN036			
Cr	ntains				-				
	intains				-				
	intains				-				
	ackaging								
Pa			Package Des	cription		Marketin	-		eting End Date
P ä #	ackaging	I 2 in 1 CARTO	-	cription			-		_
P ä #	Ackaging Item Code NDC:65162-	2 in 1 CARTO	-		bination	Dat	-		_
P a # 1	Ackaging Item Code NDC:65162-	2 in 1 CARTO 10 in 1 BLIS Product 1 in 1 CARTO	DN TER PACK; Type (DN	D: Not a Com		Dat	-		_
P a # 1 2 2	Ackaging Item Code NDC:65162- 036-02 NDC:65162- 036-03	2 in 1 CARTO 10 in 1 BLIS Product 1 in 1 CARTO	DN TER PACK; Type (D: Not a Com		Dat	-		_
Pa # 1 2 2	Ackaging Item Code NDC:65162- 036-02	2 in 1 CARTO 10 in 1 BLIS Product 1 in 1 CARTO 30 in 1 BOT Product 1 in 1 CARTO	DN TER PACK; Type (DN TLE; Type 0: Not	0: Not a Com a Combinatic	on	Dat	-		-
Pa # 1 2 2 3	Ackaging Item Code NDC:65162- 036-02 NDC:65162- 036-03	2 in 1 CARTO 10 in 1 BLIS Product 1 in 1 CARTO 30 in 1 BOT Product 1 in 1 CARTO	DN TER PACK; Type (DN TLE; Type 0: Not	0: Not a Com a Combinatic	on	Dat 07/27/2018 07/27/2018	-		_
Pa # 1 2 2 3	Ackaging Item Code NDC:65162- 036-02 NDC:65162- 036-03	2 in 1 CARTO 10 in 1 BLIS Product 1 in 1 CARTO 30 in 1 BOT Product 1 in 1 CARTO 60 in 1 BOT	DN TER PACK; Type (DN TLE; Type 0: Not	0: Not a Com a Combinatic	on	Dat 07/27/2018 07/27/2018	-		_
Pa # 1 2 3 3	Ackaging Item Code NDC:65162- 036-02 NDC:65162- 036-03	2 in 1 CARTO 10 in 1 BLIS Product 1 in 1 CARTO 30 in 1 BOT Product 1 in 1 CARTO 60 in 1 BOT Product	DN TER PACK; Type (DN TLE; Type 0: Not DN TLE; Type 0: Not	0: Not a Com a Combinatic	on	Dat 07/27/2018 07/27/2018	-		_
Pa # 1 2 3 3	Ackaging Item Code NDC:65162- 036-02 NDC:65162- 036-03 NDC:65162- 036-06	2 in 1 CARTO 10 in 1 BLIS Product 1 in 1 CARTO 30 in 1 BOT Product 1 in 1 CARTO 60 in 1 BOT Product Informa	DN TER PACK; Type (DN TLE; Type 0: Not DN TLE; Type 0: Not	0: Not a Com a Combinatic a Combinatic	on on	Dat 07/27/2018 07/27/2018	e g Start	Mark	eting End Date

GUAIFENESIN

guaifenesin tablet, extended release

Route of Administration ORAL Active Ingredient/Active Moiety Active Ingredient/Active Moiety Basis of Strength Strength Strength Strength Strength Streng	Product Infor							
Active Ingredient/Active Moiety Ingredient Name Basis of Strength Strength SUAFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) GUAIFENESIN 1200 mg nactive Ingredients Strength anactive Ingredients Strength SARBOMER COPOLYMER TYPE A (UNII: 71D05V995L) SILICON DIOXIDE (UNII: 671726X8UA) Eac BLUE NO. 1 (UNII: 670776150) Sac BLUE NO. 1 (UNII: 7009776150) ACTOSE MONOHYDRATE (UNII: 7009776150) AGRESIUM STEARATE (UNII: 7009776150) Product Characteristics Streey Size Scient Diversion Size 202mm Size 2	Product Type		HUMAN OTC DRUG	ltem Code (em Code (Source) NDC:65162-037			
Ingredient Name Basis of Strength Strength GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) GUAIFENESIN 1200 mg nactive Ingredients Ingredient Name Strength ractive Ingredients Ingredient Name Strength CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L) Strength Strength Strength COPOLYMER TYPE A (UNII: 71DD5V995L) Strength Strength Strength Strength CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L) Strength Strength Strength Strength <	Route of Administration ORAL							
Ingredient Name Basis of Strength Strength GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) GUAIFENESIN 1200 mg nactive Ingredients Ingredient Name Strength ractive Ingredients Ingredient Name Strength CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L) Strength Strength Strength COPOLYMER TYPE A (UNII: 71DD5V995L) Strength Strength Strength Strength CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L) Strength Strength Strength Strength <								
BUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) GUAIFENESIN 1200 mg nactive Ingredients Strength Strength CABBOMER COPOLYMER TYPE A (UNII: 71DD5V995L) Strength	Active Ingredi							
Ingredient Name Strength		-		F 4511(0)				
Ingredient Name Strength CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L) CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L) Strength	GUAIFENESIN (UNI	1: 49500/4510Q)	GUAIFENESIN - UNII:495V	//431VQ)	GUAIFENESIN		1200 mg	
CARBOMER COPOLYMER TYPE A (UNII: 71D55/995L) Image: Copolymer type a (UNII: 71D55/995L) Image: Copolymer type a (UNII: 71D55/995L) SILICON DIOXIDE (UNII: ET/726XBU4) Image: Copolymer type a (UNII: 30x9293WO) Image: Copolymer type a (UNII: 30x9293WO) ACTOSE MONOHYDRATE (UNII: 70097766130) Image: Copolymer type a (UNII: 70097766130) Image: Copolymer type a (UNII: 75097766130) CELULOSE, MICROCRYSTALLINE (UNII: 00917832D61U) Image: Copolymer type a (UNII: 7529734R1U) Image: Copolymer type a (UNII: 7529734R1U) Product Characteristics Score no score Shape OVAL Size 22mm Product Characteristics Imprint Code AN037 Contains OVAL Size 22mm Processing Imprint Code AN037 Product Package Description 07/27/2018 Marketing End Date MDC:65162- 037-28 2 in 1 CARTON 07/27/2018 Imprint Code Imprint Code MDC:65162- 037-38 1 in 1 CARTON 07/27/2018 Imprint Code Imprint Code Imprint Code MDC:65162- 037-06 1 in 1 CARTON 07/27/2018 Imprint Code Imprint Code Imprint Code Imprint Code Imprint Code Imprint Code	Inactive Ingre	dients						
SILICON DIOXIDE (UNII: ETJ7Z 6XBU4) ····································			•			S	trength	
PAC BLUE NO. 1 (UNII: H3R47K3TBD) Image: Constant of the second of								
ATTORELLOSES (UNII: 3NXW29V3WO) Image: Signed Start Sta		-						
ACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X) Image: Constant of the second								
EELULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) POVIDONE (UNII: FZ 989GH94E) TALC (UNII: 7SEV7J4R1U) Product Charsteristics Color blue (light blue) Score no score Shape OVAL Size 22mm Imprint Code 22mm Morregan AN037 Contains AN037 Package Description Marketing Start Date AN037 Package Description 07/27/2018 Marketing Start Date Anone Norregan Anone N								
POVIDONE (UNNI: FZ 989GH94E) Image: Second State	MAGNESIUM STEA	RATE (UNII: 70	097M6I30)					
ALC (UNII: 7SEV7J4R1U) oduct Charsteristics oluc (light blue) Score no score OVAL Score no score OVAL Score no score Imprint Code AN037 OVAL Marketing Start Marketing Start Marketing End Date Imprint Code Score 22mm AN037 Colspan="2">Score 22mm AN037 Score Score 22mm Score Marketing Start Marketing End Date Score: 07/27/2018 Score: Score: Marketing Start Marketing Start Marketing End Date Score: Score: Score: Score: Score: Score: Score: Score: Score:	CELLULOSE, MICP	OCRYSTALLIN	E (UNII: OP1R32D61U)					
Product Characteristics Score no score Shape OVAL Size 22mm Havor Imprint Code AN037 Contains - - - Hamprint Code Marketing Start Marketing End Date Marketing End Date NDC:65162- 037-28 2 in 1 CARTON 07/27/2018 07/27/2018 NDC:65162- 037-03 1 in 1 BLISTER PACK; Type 0: Not a Combination Product 07/27/2018 07/27/2018 NDC:65162- 037-03 1 in 1 CARTON 07/27/2018 07/27/2018 07/27/2018 NDC:65162- 037-03 1 in 1 CARTON 07/27/2018 07/27/2018 07/27/2018 NDC:65162- 037-03 1 in 1 CARTON 07/27/2018 07/27/2018 07/27/2018								
Color blue (light blue) Score no score Shape OVAL Size 22mm Imprint Code AN037 Anos of the state	TALC (UNII: 7SEV7J	4R1U)						
Color blue (light blue) Score no score Shape OVAL Size 22mm Imprint Code AN037 Anos of the state								
Bise Size 22mm Imprint Code AN037 Contains An037 Package Description Marketing Start Marketing End Date NDC:65162- 037-28 2 in 1 CARTON 07/27/2018 NDC:65162- 037-03 1 in 1 BLISTER PACK; Type 0: Not a Combination Product 07/27/2018 NDC:65162- 037-03 1 in 1 CARTON 07/27/2018								
Imprint Code AN037 Flavor Contains AN037 Contains Marketing Start Item Code Package Description Marketing Start Marketing End Date NDC:65162- 037-28 2 in 1 CARTON In DC:65162- 037-03 2 in 1 CARTON In DC:65162- 037-03 1 in 1 CLARTON In DC:65162- 037-03 1 in 1 CARTON In DC:65162- 037-05 1 in 1 CARTON	Product Chara	acteristics						
King Contains Marketing Start Marketing End Kem Code Package Description Marketing Start Marketing End NDC:65162- 037-28 2 in 1 CARTON 07/27/2018 Offer Contained Implementation Offer Contains Marketing Start Marketing End Implementation Offer Contained Offer Contained Marketing End Implementation Offer Contained Offer Contained Marketing End Implementation Offer Contained Offer Contained Offer Contained Implementation Offer Contained Marketing End Date Implementation Offer Contained Offer Contained Offer Contained Implementation Offer Contained Offer Contained Offer Contained Implementation Offer Contained Offer Contained Offer Contained Implementation Offer Contained Offer Contained Offer Contained Offer Contained Implementation Offer Contained Offer Contained Offer Contained Offer Contained Offer Contained Implementation Offer Contained Offer Contained Offer Contained Offer Contained	Color	blue (ligh	nt blue)			no sco	re	
Value Package Description Marketing Start Date Marketing End Date NDC:65162- 037-28 2 in 1 CARTON 07/27/2018 Of/27/2018 Image: NDC:65162- 037-03 14 in 1 BLISTER PACK; Type 0: Not a Combination Product Of/27/2018 Image: NDC:65162- 037-03 1 in 1 CARTON Image: NDC:65162- 037-03 1 in 1 CARTON Of/27/2018 Image: NDC:65162- 037-03 1 in 1 CARTON Image: NDC:65162- 037-06 1 in 1 CARTON Of/27/2018 Image: NDC:65162- 07/27/2018 Image: NDC:65162- 07/27/2018	Color Shape	blue (ligh	nt blue)	Size		22mm	re	
#Item CodePackage DescriptionMarketing Start DateMarketing End DateNDC:65162- 037-282 in 1 CARTON07/27/201807/27/2018I14 in 1 BLISTER PACK; Type 0: Not a Combination Product07/27/201807/27/2018INDC:65162- 037-031 in 1 CARTON07/27/201807/27/2018INDC:65162- 037-031 in 1 CARTON07/27/201807/27/2018INDC:65162- 037-061 in 1 CARTON07/27/201807/27/2018INDC:65162- 037-061 in 1 CARTON07/27/201807/27/2018	Color Shape Flavor	blue (ligh	nt blue)	Size	5	22mm	re	
#Item CodePackage DescriptionMarketing Start DateMarketing End DateNDC:65162- 037-282 in 1 CARTON07/27/201807/27/2018I14 in 1 BLISTER PACK; Type 0: Not a Combination Product07/27/201807/27/2018INDC:65162- 037-031 in 1 CARTON07/27/201807/27/2018INDC:65162- 037-031 in 1 CARTON07/27/201807/27/2018INDC:65162- 037-061 in 1 CARTON07/27/201807/27/2018INDC:65162- 037-061 in 1 CARTON07/27/201807/27/2018	Color Shape Flavor	blue (ligh	nt blue)	Size	2	22mm	re	
Item CodePackage DescriptionDateDateNDC:65162- 037-282 in 1 CARTON07/27/201807/27/2018I14 in 1 BLISTER PACK; Type 0: Not a Combination Product07/27/201807/27/2018INDC:65162- 037-031 in 1 CARTON07/27/201807/27/2018INDC:65162- 037-031 in 1 CARTON07/27/201807/27/2018INDC:65162- 037-061 in 1 CARTON07/27/201807/27/2018INDC:65162- 037-061 in 1 CARTON07/27/201807/27/2018	Color Shape Flavor	blue (ligh	nt blue)	Size	3	22mm	re	
037-282 IN FICARION07/27/2018I14 in 1 BLISTER PACK; Type 0: Not a Combination Product07/27/2018INDC:65162- 037-031 in 1 CARTON07/27/2018I30 in 1 BOTTLE; Type 0: Not a Combination Product07/27/2018INDC:65162- 037-061 in 1 CARTON07/27/2018INDC:65162- 037-061 in 1 CARTON07/27/2018INDC:65162- 037-061 in 1 CARTON07/27/2018	Color Shape Flavor Contains	blue (ligh	nt blue)	Size	5	22mm	re	
ProductProductProductNDC:65162- 037-031 in 1 CARTON07/27/2018NDC:65162- 037-0630 in 1 BOTTLE; Type 0: Not a Combination ProductO7/27/2018NDC:65162- 037-061 in 1 CARTON07/27/2018ODC:65162- 037-061 in 1 CARTONO7/27/2018	Color Shape Flavor Contains Packaging	blue (ligh		Size Imprint Code	rketing Start	22mm AN037	eting End	
2037-031 III 1 CARTON07/27/2018230 in 1 BOTTLE; Type 0: Not a Combination Product07/27/20183NDC:65162- 037-061 in 1 CARTON07/27/2018460 in 1 BOTTLE; Type 0: Not a Combination07/27/2018	Color Shape Flavor Contains Packaging # Item Code	blue (ligh OVAL		Size Imprint Code Ma	rketing Start Date	22mm AN037	eting End	
Product Product NDC:65162- 037-06 1 in 1 CARTON 07/27/2018 60 in 1 BOTTLE; Type 0: Not a Combination 07/27/2018	Color Shape Flavor Contains Packaging # Item Code 1 NDC:65162- 037-28	2 in 1 CARTON 14 in 1 BLISTEF	ckage Description	Size Imprint Code Ma 07/27	rketing Start Date	22mm AN037	eting End	
037-06 1 III 1 CARTON 07/27/2018 60 in 1 BOTTLE; Type 0: Not a Combination 60	Color Shape Flavor Contains Packaging # Item Code 1 NDC:65162- 037-28 1 NDC:65162-	2 in 1 CARTON 14 in 1 BLISTER Product	ckage Description	Size Imprint Code Ma 07/27	rketing Start Date /2018	22mm AN037	eting End	
	Color Shape Flavor Contains Packaging # Item Code 1 NDC:65162- 037-28 1 NDC:65162- 037-03 2 NDC:65162- 037-03	Pa 2 in 1 CARTON 14 in 1 BLISTER Product 1 in 1 CARTON 30 in 1 BOTTLE	ckage Description R PACK; Type 0: Not a Com	Size Imprint Code Ma 07/27 bination	rketing Start Date /2018	22mm AN037	eting End	
	Color Shape Flavor Contains PCKaging Item Code NDC:65162- 037-28 NDC:65162- 037-03 NDC:65162- 037-03 NDC:65162- 037-03	Pa 2 in 1 CARTON 14 in 1 BLISTEF Product 1 in 1 CARTON 30 in 1 BOTTLE Product	ckage Description R PACK; Type 0: Not a Com	Size Imprint Code Ma 07/27 bination 07/27	rketing Start Date /2018	22mm AN037	eting End	
	Color Shape Flavor Contains PCKaging Item Code NDC:65162- 037-28 NDC:65162- 037-03 NDC:65162- 037-03 NDC:65162- 037-03	Pa 2 in 1 CARTON 14 in 1 BLISTEF Product 1 in 1 CARTON 30 in 1 BOTTLE Product 1 in 1 CARTON 60 in 1 BOTTLE	ckage Description R PACK; Type 0: Not a Com	Size Imprint Code Ma 07/27 bination 07/27	rketing Start Date /2018	22mm AN037	eting End	
Marketing Information	Color Shape Flavor Contains Exaging Item Code NDC:65162- 037-28 NDC:65162- 037-03 2 NDC:65162- 037-03 2 3 NDC:65162- 037-06	Pa 2 in 1 CARTON 14 in 1 BLISTEF Product 1 in 1 CARTON 30 in 1 BOTTLE Product 1 in 1 CARTON 60 in 1 BOTTLE	ckage Description R PACK; Type 0: Not a Com	Size Imprint Code Ma 07/27 bination 07/27	rketing Start Date /2018	22mm AN037	eting End	

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	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