

**MAXIMUM STRENGTH MUCINEX FAST-MAX DAY COLD AND FLU AND NIGHT COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, guaifenesin, and phenylephrine hydrochloride
RB Health (US) LLC**

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Maximum Strength Mucinex® Fast-Max® Day Cold and Flu and Night Cold and Flu

Drug Facts

Active ingredients (in each liquid gel) Purposes

Mucinex FAST-MAX DAY Cold & Flu

Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

Active ingredients (in each liquid gel) Purposes

Mucinex FAST-MAX NIGHT Cold & Flu

Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Doxylamine succinate 6.25 mg	Antihistamine
Phenylephrine HCl 5 mg	Nasal decongestant

Uses

- temporarily relieves these common cold and flu symptoms:
 - sinus congestion and pressure
 - cough
 - minor aches and pains
 - headache
 - nasal congestion
 - sore throat
 - runny nose (**NIGHT only**)

- sneezing (**NIGHT only**)
- itching of the nose or throat (**NIGHT only**)
- itchy, watery eyes due to hay fever (**NIGHT only**)
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive (**DAY only**)
- controls cough to help you get to sleep
- temporarily reduces fever

Warnings

Liver warning

This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 12 liquid gels in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily while using this product

Allergy alert

Acetaminophen may cause severe skin reactions.

Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Sore throat warning

If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- 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 an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- liver disease
- heart disease
- diabetes
- high blood pressure
- thyroid disease
- trouble urinating due to an enlarged prostate gland
- glaucoma (**NIGHT only**)

- a breathing problem such as emphysema or chronic bronchitis (**NIGHT only**)
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough that occurs with too much phlegm (mucus)

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers (**NIGHT only**)

When using this product

- **do not use more than directed**
- excitability may occur, especially in children (**NIGHT only**)
- marked drowsiness may occur (**NIGHT only**)
- alcohol, sedatives, and tranquilizers may increase drowsiness (**NIGHT only**)
- avoid alcoholic drinks (**NIGHT only**)
- be careful when driving a motor vehicle or operating machinery (**NIGHT only**)

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, or cough gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

Overdose warning

Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- **do not take more than directed (see Overdose warning)**
- do not take more than 12 liquid gels in any 24-hour period
- adults and children 12 years of age and over: take 2 liquid gels every 4 hours
- children under 12 years of age: do not use

Other information

- store at 20-25°C (68-77°F)
- avoid excessive heat

Inactive ingredients (DAY only)

FD&C yellow no. 6, gelatin, glycerin, lecithin (soy), mineral oil, polyethylene glycol, povidone, propylene glycol, purified water, shellac, sorbitol sorbitan solution, titanium dioxide

Inactive ingredients (NIGHT only)

D&C yellow no. 10, FD&C blue no. 1, gelatin, glycerin, lecithin (soy), mineral oil, polyethylene glycol, povidone, propylene glycol, purified water, shellac, sorbitol sorbitan solution, titanium dioxide

Questions?

1-866-MUCINEX (1-866-682-4639)

You may also report side effects to this phone number.

Dist. by: RB Health (US)
Parsippany, NJ 07054-0224

Made in China

PRINCIPAL DISPLAY PANEL - Kit Carton

Fast Dissolving Liquid Gels!

MAXIMUM STRENGTH

NDC 63824-519-24

Mucinex®

FAST-MAX®

DAY

COLD & FLU

Acetaminophen – Pain Reliever/Fever Reducer

Dextromethorphan HBr – Cough Suppressant

Guaifenesin – Expectorant

Phenylephrine HCl – Nasal Decongestant

HEADACHE

BODY PAIN

SORE THROAT

FEVER

CHEST CONGESTION

COUGH

ALL IN

ONE *

NASAL CONGESTION

SINUS CONGESTION

SINUS PRESSURE

16

LIQUID GELS

(Liquid Filled

Capsules)

NIGHT

COLD & FLU

Acetaminophen – Pain Reliever/Fever Reducer

Dextromethorphan HBr – Cough Suppressant

Doxylamine succinate - Antihistamine

Phenylephrine HCl – Nasal Decongestant

HEADACHE

BODY PAIN

SORE THROAT

FEVER

ITCHY THROAT

COUGH

ALL IN

ONE *

NASAL CONGESTION

SNEEZING

RUNNY NOSE

8

LIQUID GELS

(Liquid Filled

Capsules)

24 TOTAL

AGES 12+

MAXIMUM STRENGTH

VALUE PACK

24 LIQUID GELS

Mucinex®

FAST-MAX®

DAY COLD & FLU **NIGHT COLD & FLU**

Tamper evident: Do not use if carton is damaged or if printed seal on blister is broken or missing.

Fast Dissolving Liquid Gels!

MAXIMUM STRENGTH NDC 63824-519-24

Mucinex®

FAST-MAX®

DAY COLD & FLU **NIGHT COLD & FLU**

Acetaminophen – Pain Reliever/Fever Reducer
Dextromethorphan HBr – Cough Suppressant
Guafenesin – Expectorant
Phenylephrine HCl – Nasal Decongestant

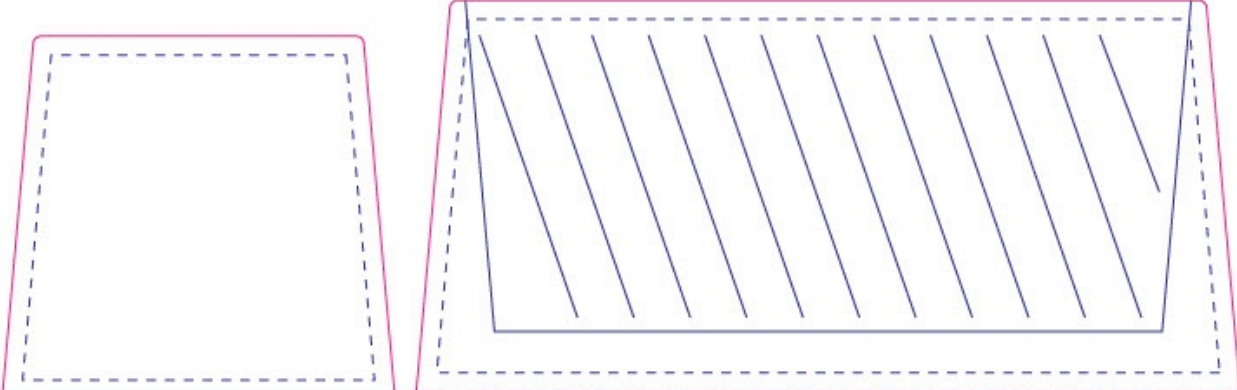
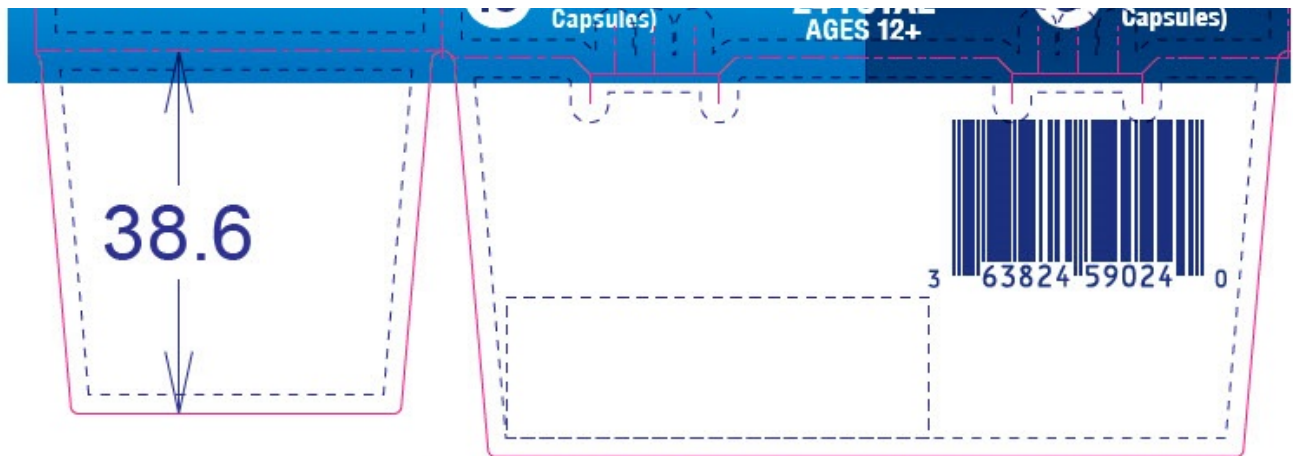
Acetaminophen – Pain Reliever/Fever Reducer
Dextromethorphan HBr – Cough Suppressant
Doxylamine succinate – Antihistamine
Phenylephrine HCl – Nasal Decongestant

ALL IN ONE*

ALL IN ONE*

16 LIQUID GELS (Liquid Filled) **24 TOTAL** **8 LIQUID GELS (Liquid Filled)**

PARENTS:
 Learn about teen medicine abuse
www.StopMedicineAbuse.org



Drug Facts

Active ingredients (in each liquid gel) Purposes
Mucinex FAST-MAX DAY Cold & Flu

Acetaminophen 325 mg...Pain reliever/fever reducer
 Dextromethorphan HBr 10 mg.....Cough suppressant
 Guaifenesin 200 mg.....Expectorant
 Phenylephrine HCl 5 mg.....Nasal decongestant

Active ingredients (in each liquid gel) Purposes
Mucinex FAST-MAX NIGHT Cold & Flu

Acetaminophen 325 mg...Pain reliever/fever reducer
 Dextromethorphan HBr 10 mg.....Cough suppressant
 Doxylamine succinate 6.25 mg.....Antihistamine
 Phenylephrine HCl 5 mg.....Nasal decongestant

Uses ■ temporarily relieves these common cold and flu symptoms:
 ■ sinus congestion and pressure
 ■ cough ■ minor aches and pains
 ■ headache ■ nasal congestion ■ sore throat
 ■ runny nose (NIGHT only) ■ sneezing (NIGHT only)
 ■ itching of the nose or throat (NIGHT only)
 ■ itchy, watery eyes due to hay fever (NIGHT only)
 ■ helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive (DAY only)
 ■ controls cough to help you get to sleep
 ■ temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:
 ■ more than 12 liquid gels in 24 hours, which is the maximum daily amount
 ■ with other drugs containing acetaminophen
 ■ 3 or more alcoholic drinks daily while using this product
Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin reddening ■ blisters ■ rash
 If a skin reaction occurs, stop use and seek medical help right away.
Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use ■ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
 ■ 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 an MAOI, ask a doctor or pharmacist before taking this product.

Drug Facts (continued)

■ trouble urinating due to an enlarged prostate gland
 ■ glaucoma (NIGHT only)
 ■ a breathing problem such as emphysema or chronic bronchitis (NIGHT only)
 ■ persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
 ■ cough that occurs with too much phlegm (mucus)
 Ask a doctor or pharmacist before use if you are
 ■ taking the blood thinning drug warfarin
 ■ taking sedatives or tranquilizers (NIGHT only)
 When using this product ■ do not use more than directed
 ■ excitability may occur, especially in children (NIGHT only)
 ■ marked drowsiness may occur (NIGHT only)
 ■ alcohol, sedatives, and tranquilizers may increase drowsiness (NIGHT only)
 ■ avoid alcoholic drinks (NIGHT only)
 ■ be careful when driving a motor vehicle or operating machinery (NIGHT only)

Stop use and ask a doctor if

■ nervousness, dizziness, or sleeplessness occur
 ■ pain, nasal congestion, or cough gets worse or lasts more than 7 days
 ■ fever gets worse or lasts more than 3 days
 ■ redness or swelling is present ■ new symptoms occur
 ■ cough comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children.

Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

■ do not take more than directed (see Overdose warning)
 ■ do not take more than 12 liquid gels in any 24-hour period
 ■ adults and children 12 years of age and over: take 2 liquid gels every 4 hours
 ■ children under 12 years of age: do not use

Other information

■ store at 20-25°C (68-77°F)
 ■ avoid excessive heat

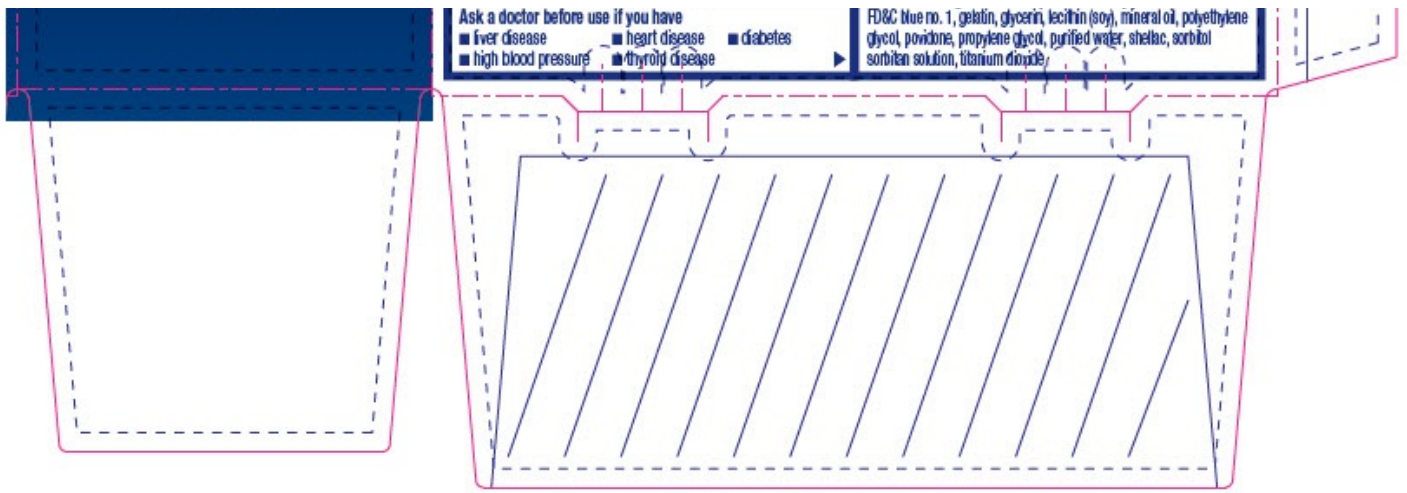
Inactive ingredients (DAY only) FD&C yellow no. 6, gelatin, glycerin, lecithin (soy), mineral oil, polyethylene glycol, povidone, propylene glycol, purified water, shellac, sorbitol sorbitan solution, titanium dioxide

Inactive ingredients (NIGHT only) D&C yellow no. 10,

Questions?
 1-866-MUCINEX (1-866-682-4639)
 You may also report side effects to this phone number.



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 www.mucinex.com
 Patents: www.rb.com/patents
 Dist. by: RB Health (US)
 Parsippany, NJ 07054-0224
 Made in China
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 020519 8357061



MAXIMUM STRENGTH MUCINEX FAST-MAX DAY COLD AND FLU AND NIGHT COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, guaifenesin, and phenylephrine hydrochloride kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63824-519
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-519-24	1 in 1 CARTON	07/28/2018	
1		1 in 1 KIT		
2	NDC:63824-519-48	2 in 1 CARTON	07/28/2018	
2		1 in 1 KIT		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	2 BLISTER PACK	16
Part 2	1 BLISTER PACK	8

Part 1 of 2

MAXIMUM STRENGTH MUCINEX FAST-MAX DAY COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride capsule, liquid filled

Product Information

Route of Administration	ORAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SHELLAC (UNII: 46N107B71O)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	orange	Score	no score
Shape	OVAL	Size	24mm
Flavor		Imprint Code	PC26
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/28/2018	

Part 2 of 2

MAXIMUM STRENGTH MUCINEX FAST-MAX NIGHT COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, and phenylephrine hydrochloride capsule, liquid filled

Product Information

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
DOXYLAMINE SUCCINATE (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SHELLAC (UNII: 46N107B71O)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	green	Score	no score
Shape	OVAL	Size	20mm
Flavor		Imprint Code	VVV;CF
Contains			

Packaging

Item	Marketing Start	Marketing End
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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/28/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/28/2018	

Labeler - RB Health (US) LLC (081049410)

Revised: 5/2022

RB Health (US) LLC