

**MUCINEX FAST-MAX DAY SEVERE CONGESTION AND COUGH AND MUCINEX NIGHTSHIFT NIGHT COLD AND FLU MAXIMUM STRENGTH- acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride, and triprolidine 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.*

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**Mucinex® Fast-Max® Day Severe Congestion & Cough and Mucinex Nightshift Night Cold & Flu**

**Maximum Strength**

**Drug Facts**

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**Active ingredients (in each caplet)**

**Mucinex Fast-Max Day Severe Congestion & Cough**

**Purposes**

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Dextromethorphan HBr 10 mg	Cough suppressant
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

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**Active ingredients (in each caplet)**

**Mucinex Nightshift Night Cold & Flu**

**Purposes**

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Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Tripolidine HCl 1.25 mg	Antihistamine

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**Uses**

**Mucinex Fast-Max Day Severe Congestion & Cough**

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily relieves:
  - cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
  - the impulse to cough to help you get to sleep
  - the intensity of coughing
  - nasal congestion due to a cold

## **Mucinex Nightshift Night Cold & Flu**

- temporarily relieves these common cold and flu symptoms:
  - cough
  - minor aches and pains
  - sore throat
  - headache
  - runny nose
  - sneezing
  - itching of the nose or throat
  - itchy, watery eyes due to hay fever
- temporarily reduces fever
- controls cough to help you get to sleep

## **Warnings**

### **Liver warning (Nightshift Night Cold & Flu only)**

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

- more than 4,000 mg 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 (Nightshift Night Cold & Flu only)**

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 (Nightshift Night Cold & Flu only)**

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. **(Nightshift Night Cold & Flu only)**
- 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 **(Nightshift Night Cold & Flu only)**
- heart disease **(Fast-Max Day Severe Congestion & Cough only)**
- high blood pressure **(Fast-Max Day Severe Congestion & Cough only)**
- thyroid disease **(Fast-Max Day Severe Congestion & Cough only)**

- diabetes (**Fast-Max Day Severe Congestion & Cough only**)
- glaucoma (**Nightshift Night Cold & Flu only**)
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis (**Nightshift Night Cold & Flu 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 (**Nightshift Night Cold & Flu only**)
- taking sedatives or tranquilizers (**Nightshift Night Cold & Flu only**)

**When using this product**

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

**Stop use and ask a doctor if**

- pain or cough gets worse or lasts more than 7 days (**Nightshift Night Cold & Flu only**)
- fever gets worse or lasts more than 3 days (**Nightshift Night Cold & Flu only**)
- redness or swelling is present (**Nightshift Night Cold & Flu only**)
- new symptoms occur (**Nightshift Night Cold & Flu only**)
- cough comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition. (**Nightshift Night Cold & Flu only**)
- nervousness, dizziness, or sleeplessness occur (**Fast-Max Day Severe Congestion & Cough only**)
- symptoms do not get better within 7 days or occur with fever (**Fast-Max Day Severe Congestion & Cough only**)
- cough lasts more than 7 days, comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition. (**Fast-Max Day Severe Congestion & Cough only**)

**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.

**Overdose warning (Nightshift Night Cold & Flu only)**

Taking more than the recommended dose (overdose) may cause liver damage. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

## Directions

### **Mucinex Fast-Max Day Severe Congestion & Cough**

- **do not take more than directed**
- do not take more than 12 caplets in any 24-hour period
- adults and children 12 years of age and over: take 2 caplets every 4 hours
- children under 12 years of age: do not use

### **Mucinex Nightshift Night Cold & Flu**

- **do not take more than directed (see Overdose warning)**
- do not take more than 8 caplets in any 24-hour period
- adults and children 12 years of age and over: take 2 caplets every 4 hours
- children under 12 years of age: do not use

## Other information

- store at 20-25°C (68-77°F)

### **Inactive ingredients Mucinex Fast-Max Day Severe Congestion & Cough**

croscarmellose sodium, FD&C blue no. 2 aluminum lake, FD&C red no. 40 aluminum lake, methacrylic acid-ethyl acrylate copolymer, mica, microcrystalline cellulose, polyethylene glycol 3350, polysorbate 80, polyvinyl alcohol, povidone K29/32, sodium bicarbonate, talc, titanium dioxide

### **Inactive ingredients Mucinex Nightshift Night Cold & Flu**

croscarmellose sodium, crospovidone, hypromellose, microcrystalline cellulose, polyethylene glycol, polysorbate 80, povidone, 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

## **PRINCIPAL DISPLAY PANEL - Kit Carton**

FAST RELEASE. POWERFUL SYMPTOM RELIEF!

NDC 72854-242-40

MAXIMUM STRENGTH

Mucinex®

FAST-MAX® NIGHTSHIFT

DAY

SEVERE CONGESTION  
& COUGH

Dextromethorphan HBr - Cough Suppressant

Guaifenesin - Expectorant

Phenylephrine HCl - Nasal Decongestant

- Controls Cough
- Relieves Nasal & Chest  
Congestion
- Thins & Loosens Mucus

ACTUAL SIZE

FOR AGES 12+

24 CAPLETS

NIGHT

COLD & FLU

Acetaminophen - Pain Reliever/

Fever Reducer

Dextromethorphan HBr - Cough Suppressant

Triprolidine HCl - Antihistamine

NIGHTTIME

RELIEF FOR A BETTER

MORNING

✓COUGH ✓FEVER ✓SORE THROAT

✓RUNNY NOSE ✓SNEEZING

ACTUAL SIZE

FOR AGES 12+

16 CAPLETS

FAST

RELEASE

TOTAL 40 CAPLETS

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

MAXIMUM STRENGTH

**Mucinex**  
FAST-MAX NIGHTSHIFT

**DAY**  
SEVERE  
CONGESTION  
& COUGH

**NIGHT**  
COLD & FLU

FAST RELEASE. POWERFUL SYMPTOM RELIEF

MAXIMUM STRENGTH

NDC 72854-242-40

**Mucinex**  
FAST-MAX NIGHTSHIFT

**DAY**  
SEVERE CONGESTION  
& COUGH

**NIGHT**  
COLD & FLU

Dextromethorphan HBr – Cough Suppressant  
Guaifenesin – Expectorant  
Phenylephrine HCl – Nasal Decongestant

Acetaminophen – Pain Reliever/  
Fever Reducer  
Dextromethorphan HBr – Cough Suppressant  
Triproline HCl – Antihistamine

- ✓ Controls Cough
- ✓ Relieves Nasal & Chest Congestion
- ✓ Thins & Loosens Mucus



- ✓ COUGH ✓ FEVER ✓ SORE THROAT
- ✓ RUNNY NOSE ✓ SNEEZING

ACTUAL SIZE

FOR AGES 12+

**FAST  
RELEASE**

ACTUAL SIZE

FOR AGES 12+

**24** CAPLETS

TOTAL 40 CAPLETS

**16** CAPLETS

LOT:

EXP.:

MADE IN:

3176349



SEVERE  
CONGESTION  
& COUGH

**DAY**

**NIGHT**  
COLD & FLU

**Mucinex**  
FAST-MAX NIGHTSHIFT

MAXIMUM STRENGTH

Maximum Strength per 4-hour dose  
Do not take the Mucinex Fast-Max Day Severe  
Congestion & Cough and Mucinex Nightshift Night  
Cold & Flu caplets at the same time. Always wait at  
least 4 hours before taking another dose of Mucinex  
caplets.  
TAKE ONLY AS DIRECTED.  
Keep carton for full information.

**PARENTS:**  
Learn about how medicine works  
[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)

Questions?

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



HEALTH • HYGIENE • HOME

[www.mucinex.com](http://www.mucinex.com)

Patents: [www.rb.com/patents](http://www.rb.com/patents)

Dist. by: RB Health (US)  
Parsippany, NJ 07054-0224  
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Do not take the Mucinex Fast-Max Day Severe Congestion & Cough and Mucinex Nightshift Night Cold & Flu caplets at the same time. Always wait at least 4 hours before taking another dose of Mucinex caplets. TAKE ONLY AS DIRECTED.

3176349 1230

**Drug Facts**

Active ingredients (in each caplet)	Purposes
<b>Mucinex Fast-Max Day Severe Congestion &amp; Cough</b>	
Dextromethorphan HBr 10 mg.....	Cough suppressant
Guaifenesin 200 mg.....	Expectorant
Phenylephrine HCl 5 mg.....	Nasal decongestant
<b>Active ingredients (in each caplet)</b>	<b>Purposes</b>

**Mucinex Nightshift Night Cold & Flu**

Acetaminophen 325 mg.....	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg.....	Cough suppressant
Triprolidine HCl 1.25 mg.....	Antihistamine

**Uses**

**Mucinex Fast-Max Day Severe Congestion & Cough**

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily relieves:
  - cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
  - the impulse to cough to help you get to sleep
  - the intensity of coughing
  - nasal congestion due to a cold

**Mucinex Nightshift Night Cold & Flu**

- temporarily relieves these common cold and flu symptoms:
  - cough
  - minor aches and pains
  - sore throat
  - headache
  - runny nose
  - sneezing
  - itching of the nose or throat
  - itchy, watery eyes due to hay fever
- temporarily reduces fever
- controls cough to help you get to sleep

**Warnings**

**Liver warning (Nightshift Night Cold & Flu only):** This product contains acetaminophen.

- Severe liver damage may occur if you take:
- more than 4,000 mg 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 (Nightshift Night Cold & Flu only):** 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 (Nightshift Night Cold & Flu only):** 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.

**Reseal Area**

**Drug Facts (continued)**

**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. **(Nightshift Night Cold & Flu only)**
- 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 **(Nightshift Night Cold & Flu only)**
- heart disease **(Fast-Max Day Severe Congestion & Cough only)**
- high blood pressure **(Fast-Max Day Severe Congestion & Cough only)**
- thyroid disease **(Fast-Max Day Severe Congestion & Cough only)**
- diabetes **(Fast-Max Day Severe Congestion & Cough only)**
- glaucoma **(Nightshift Night Cold & Flu only)**
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis **(Nightshift Night Cold & Flu 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 **(Nightshift Night Cold & Flu only)**
- taking sedatives or tranquilizers **(Nightshift Night Cold & Flu only)**

**When using this product**

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

**Stop use and ask a doctor if**

- pain or cough gets worse or lasts more than 7 days **(Nightshift Night Cold & Flu only)**
- fever gets worse or lasts more than 3 days **(Nightshift Night Cold & Flu only)**

Hinge

Hinge

**Drug Facts** (continued)

- redness or swelling is present (**Nightshift Night Cold & Flu only**)
- new symptoms occur (**Nightshift Night Cold & Flu only**)
- cough comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition. (**Nightshift Night Cold & Flu only**)
- nervousness, dizziness, or sleeplessness occur (**Fast-Max Day Severe Congestion & Cough only**)
- symptoms do not get better within 7 days or occur with fever (**Fast-Max Day Severe Congestion & Cough only**)
- cough lasts more than 7 days, comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition. (**Fast-Max Day Severe Congestion & Cough only**)

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.

**Overdose warning (Nightshift Night Cold & Flu only):** Taking more than the recommended dose (overdose) may cause liver damage. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

**Directions**

**Mucinex Fast-Max Day Severe Congestion & Cough**

- do not take more than directed
- do not take more than 12 caplets in any 24-hour period
- adults and children 12 years of age and over: take 2 caplets every 4 hours
- children under 12 years of age: do not use

**Mucinex Nightshift Night Cold & Flu**

- do not take more than directed (see **Overdose warning**)
- do not take more than 8 caplets in any 24-hour period
- adults and children 12 years of age and over: take 2 caplets every 4 hours
- children under 12 years of age: do not use

**Other information** ■ store at 20-25°C (68-77°F)

**Inactive ingredients Mucinex Fast-Max Day Severe Congestion & Cough**

croscarmellose sodium, FD&C blue no. 2 aluminum lake, FD&C red no. 40 aluminum lake, methacrylic acid-ethyl acrylate copolymer, mica, microcrystalline cellulose, polyethylene glycol 3350, polysorbate 80, polyvinyl alcohol, povidone K29/32, sodium bicarbonate, talc, titanium dioxide

**Inactive ingredients Mucinex Nightshift Night Cold & Flu**

croscarmellose sodium, crospovidone, hypromellose, microcrystalline cellulose, polyethylene glycol, polysorbate 80, povidone, titanium dioxide

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

**MUCINEX FAST-MAX DAY SEVERE CONGESTION AND COUGH AND MUCINEX NIGHTSHIFT NIGHT COLD AND FLU MAXIMUM STRENGTH**

acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride, and triprolidine hydrochloride kit

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72854-242
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**Packaging**



#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72854-242-40	1 in 1 CARTON	07/01/2021	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	4 BLISTER PACK	24
Part 2	4 BLISTER PACK	16

### Part 1 of 2

## MUCINEX FAST-MAX SEVERE CONGESTION AND COUGH

dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride tablet, coated

### Product Information

Item Code (Source)	NDC:63824-193
Route of Administration	ORAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>FD&amp;C BLUE NO. 2</b> (UNII: L06K8R7DQK)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)	
<b>MICA</b> (UNII: V8A1AW0880)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	red	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	VV;SCC
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		6 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	07/01/2021	

## Part 2 of 2

### MUCINEX NIGHTSHIFT COLD AND FLU MAXIMUM STRENGTH

acetaminophen, dextromethorphan hydrobromide, and triprolidine hydrochloride tablet, coated

### Product Information

<b>Item Code (Source)</b>	NDC:72854-233
<b>Route of Administration</b>	ORAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
<b>TRIPROLIDINE HYDROCHLORIDE</b> (UNII: YAN7R5L890) (TRIPROLIDINE - UNII:2L8T9S52QM)	TRIPROLIDINE HYDROCHLORIDE	1.25 mg
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>CROSPVIDONE</b> (UNII: 2S7830E561)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	

**TITANIUM DIOXIDE** (UNII: 15FIX9V2JP)

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	VV;LOGO crescentmoon
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		4 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	07/01/2021	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/01/2021	

**Labeler** - RB Health (US) LLC (081049410)

Revised: 6/2023

RB Health (US) LLC