**MUCINEX FAST MAX DAY TIME SEVERE CONGESTION AND COUGH AND NIGHT TIME COLD AND FLU- guaifenesin, phenylephrine hydrochloride, dextromethorphan hydrobromide, acetaminophen, and diphenhydrmaine 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 Time Severe Congestion & Cough and Night Time Cold & Flu**

***Drug Facts***

| ***Active ingredients (in each caplet)*** | ***Purposes*** |
|---|---|
| ***Mucinex ®FAST-MAX ®DAY TIME SEVERE CONGESTION & COUGH*** | |
| Dextromethorphan HBr 10mg | Cough suppressant |
| Guaifenesin 200mg | Expectorant |
| Phenylephrine HCl 5mg | Nasal decongestant |

| ***Active ingredients (in each caplet)*** | ***Purposes*** |
|---|---|
| ***Mucinex FAST-MAX NIGHT TIME COLD & FLU*** | |
| **Acetaminophen 325 mg** | **Pain reliever/ fever reducer** |
| Diphenhydramine HCl 12.5 mg | Antihistamine/cough suppressant |
| Phenylephrine HCl 5 mg | Nasal decongestant |

**Uses**

- temporarily relieves ***(DAY TIME only):***
  - cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
  - the intensity of coughing
  - nasal congestion due to a cold
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive ***(DAY TIME only)***
- temporarily relieves these common cold and flu symptoms ***(NIGHT TIME only):***
  - cough
  - minor aches and pains
  - headache
  - nasal congestion

- sore throat
- runny nose
- sneezing
- itching of the nose or throat
- itchy, watery eyes due to hay fever

- temporarily reduces fever ***(NIGHT TIME only)***
- controls cough to help you get to sleep

**Warnings**

**Liver warning (NIGHT TIME only)**

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

- more than 12 caplets 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 (NIGHT TIME 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 (NIGHT TIME 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. ***(NIGHT TIME only)***
- with any other product containing diphenhydramine, even one used on the skin ***(NIGHT TIME 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 ***(NIGHT TIME only)***
- heart disease
- diabetes
- high blood pressure
- thyroid disease
- trouble urinating due to an enlarged prostate gland
- glaucoma ***(NIGHT TIME only)***

- a breathing problem such as emphysema or chronic bronchitis ***(NIGHT TIME 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 ***(NIGHT TIME only)***
- taking sedatives or tranquilizers ***(NIGHT TIME only)***

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

**Stop use and ask a doctor if**
- nervousness, dizziness, or sleeplessness occur
- symptoms do not get better within 7 days or occur with fever ***(DAY TIME only)***
- pain, nasal congestion, or cough gets worse or lasts more than 7 days ***(NIGHT TIME only)***
- fever gets worse or lasts more than 3 days ***(NIGHT TIME only)***
- redness or swelling is present ***(NIGHT TIME only)***
- new symptoms occur ***(NIGHT TIME only)***
- 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.** In case of overdose, get medical help or contact a Poison Control Center right away.

**Overdose warning (NIGHT TIME 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**
- **do not take more than directed (see Overdose warning)**
- 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

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

**Inactive ingredients (Mucinex FAST-MAX DAY TIME SEVERE CONGESTION & COUGH)**

corn starch, FD&C blue no. 2 aluminum lake, FD&C red no. 40 aluminum lake, magnesium stearate, maltodextrin, mica, microcrystalline cellulose, polyethylene glycol, polysorbate 80, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, talc, titanium dioxide

**Inactive ingredients (Mucinex FAST-MAX NIGHT TIME COLD & FLU)**

corn starch, croscarmellose sodium, crospovidone, FD&C blue no. 1 aluminum lake, FD&C blue no. 2 aluminum lake, ferric oxide yellow, magnesium stearate, methacrylic acid-ethyl acrylate copolymer (1:1) type A, mica, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium bicarbonate, stearic acid, talc, titanium dioxide

**PRINCIPAL DISPLAY PANEL - Kit Carton**

MAXIMUM STRENGTH
NDC 63824-792-01

Mucinex®
FAST-Max ®

DAY
TIME
SEVERE CONGESTION
& COUGH

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

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

20 CAPLETS

FOR AGES 12+

NIGHT
TIME
COLD & FLU

Acetaminophen - Pain Reliever/Fever Reducer
Diphenhydramine HCl - Antihistamine/
Cough Suppressant
Phenylephrine HCl - Nasal Decongestant

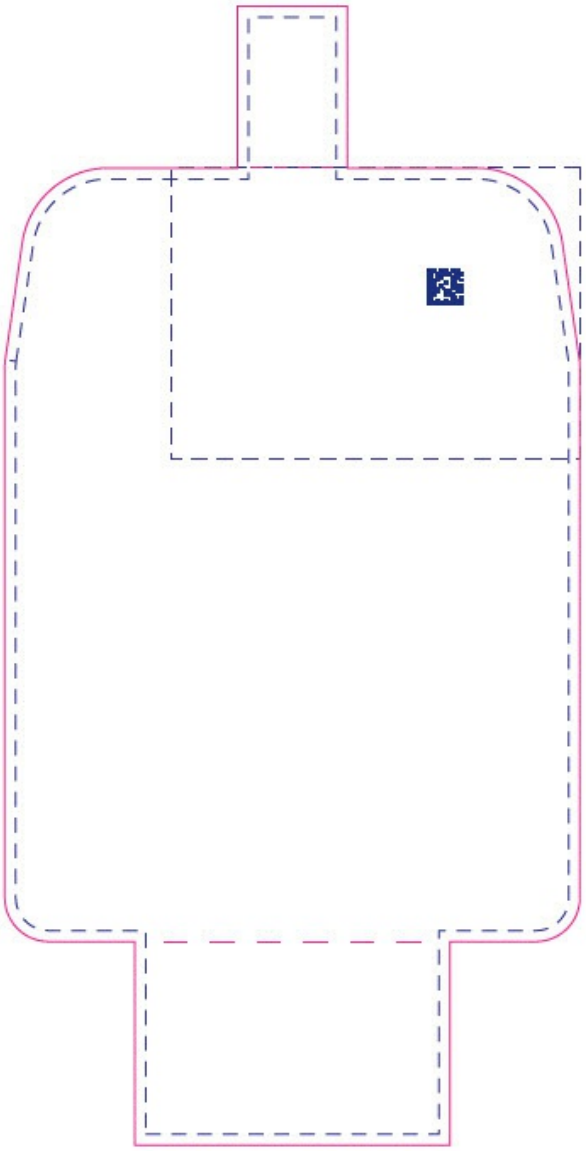
- Relieves Aches, Fever & Sore Throat
- Controls Cough

- Relieves Nasal Congestion
- Relieves Runny Nose & Sneezing

10 CAPLETS

FOR AGES 12+

TOTAL 30 CAPLETS

## Drug Facts

**Active ingredients (in each caplet)** — **Purposes**

**Mucinex® FAST-MAX® DAY TIME SEVERE CONGESTION & COUGH**

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

**Active ingredients (in each caplet)** — **Purposes**

**Mucinex FAST-MAX NIGHT TIME COLD & FLU**

| | |
|---|---|
| Acetaminophen 325 mg | Pain reliever/fever reducer |
| Diphenhydramine HCl 12.5 mg | Antihistamine/cough suppressant |
| Phenylephrine HCl 5 mg | Nasal decongestant |

**Uses**

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

## Drug Facts (continued)

**Warnings**

Liver warning *(NIGHT TIME only)*: This product contains acetaminophen. Severe liver damage may occur if you take:

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

## 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. *(NIGHT TIME only)*
- with any other product containing diphenhydramine, even one used on the skin *(NIGHT TIME 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.

## Drug Facts (continued)

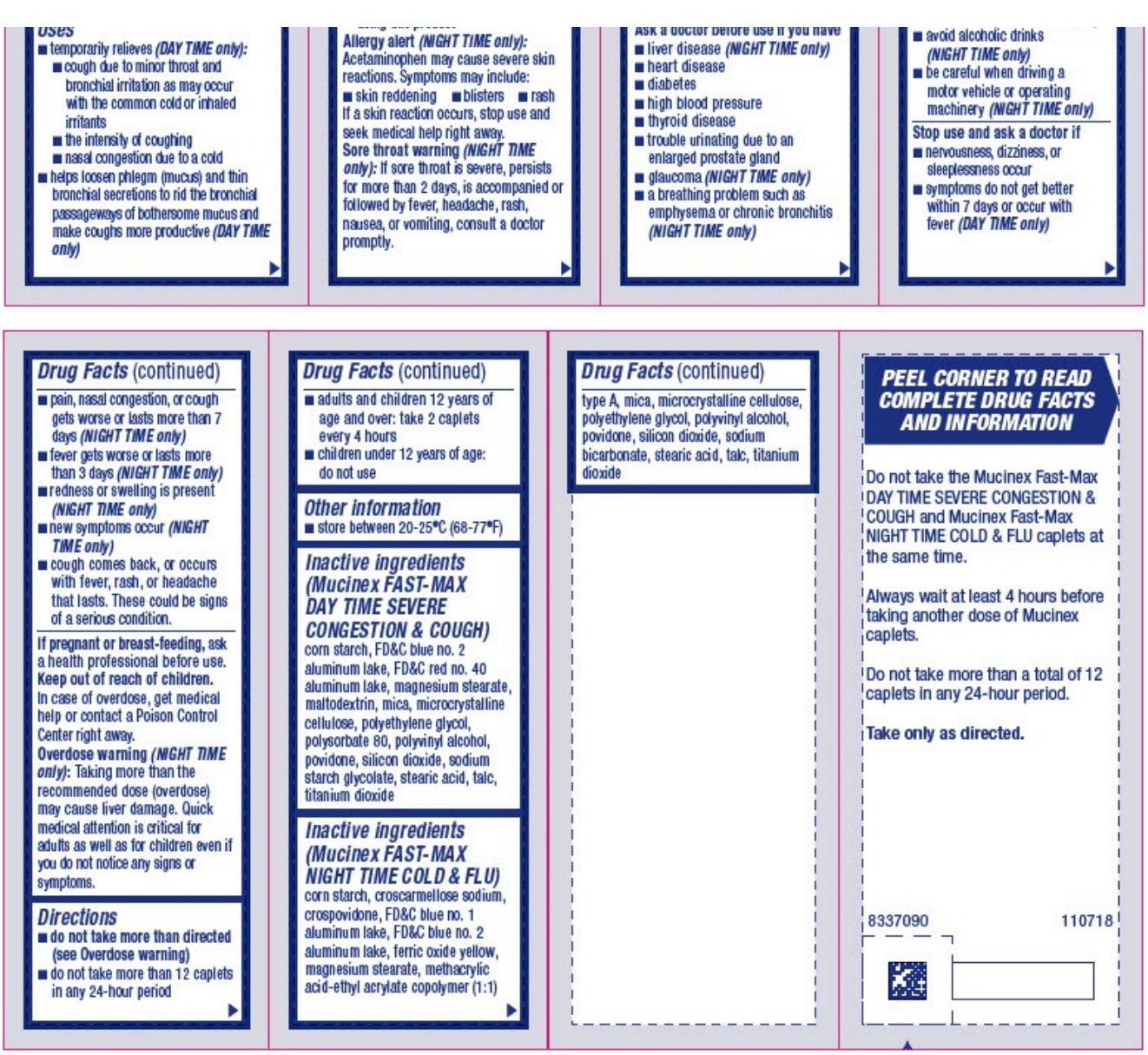
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough that occurs with too much phlegm (mucus)

**Ask a doctor or pharmacist before use if you are**

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

**When using this product**

- do not use more than directed
- excitability may occur, especially in children *(NIGHT TIME only)*
- marked drowsiness may occur *(NIGHT TIME only)*
- alcohol, sedatives, and tranquilizers may increase drowsiness *(NIGHT TIME only)*




# MUCINEX FAST MAX DAY TIME SEVERE CONGESTION AND COUGH AND NIGHT TIME COLD AND FLU

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

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:63824-792 |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:63824-792-01 | 1 in 1 PACKAGE, COMBINATION | 12/15/2018 | 02/16/2025 |

## Quantity of Parts

| Part # | Package Quantity | Total Product Quantity |
|---|---|---|
| **Part 1** | 2 BLISTER PACK | 20 |
| **Part 2** | 1 BLISTER PACK | 10 |

## Part 1 of 2

# MUCINEX FAST-MAX SEVERE CONGESTION AND COUGH

guaifenesin, phenylephrine hydrochloride, and dextromethorphan hydrobromide tablet, film coated

### Product Information

| | |
|---|---|
| **Item Code (Source)** | NDC:63824-515 |
| **Route of Administration** | ORAL |

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **FD&C BLUE NO. 2** (UNII: L06K8R7DQK) | |
| **ALUMINUM OXIDE** (UNII: LMI26O6933) | |
| **FD&C RED NO. 40** (UNII: WZB9127XOA) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **MALTODEXTRIN** (UNII: 7CVR7L4A2D) | |
| **MICA** (UNII: V8A1AW0880) | |
| **MICROCRYSTALLINE CELLULOSE** (UNII: OP1R32D61U) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **POLYSORBATE 80** (UNII: 6OZP39ZG8H) | |
| **POLYVINYL ALCOHOL, UNSPECIFIED** (UNII: 532B59J990) | |
| **POVIDONE, UNSPECIFIED** (UNII: FZ989GH94E) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **SODIUM STARCH GLYCOLATE TYPE A POTATO** (UNII: 5856J3G2A2) | |
| **STEARIC ACID** (UNII: 4ELV7Z65AP) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |

### Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | red | **Score** | no score |
| **Shape** | OVAL | **Size** | 19mm |
| **Flavor** | | **Imprint Code** | SRS |
| **Contains** | | | |

**Packaging**

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:63824-515-01 | 2 in 1 CARTON | | |
| **1** | | 10 in 1 BLISTER PACK; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product) | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph final | part341 | 08/01/2018 | |

## Part 2 of 2

## MUCINEX FAST-MAX NIGHT TIME SEVERE COLD AND FLU

acetaminophen, diphenhydramine hydrochloride, and phenylephrine hydrochloride tablet, film coated

**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 |
| **DIPHENHYDRAMINE HYDROCHLORIDE** (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M) | DIPHENHYDRAMINE HYDROCHLORIDE | 12.5 mg |
| **PHENYLEPHRINE HYDROCHLORIDE** (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 5 mg |

**Inactive Ingredients**

| Ingredient Name | Strength |
|---|---|
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **CROSCARMELLOSE SODIUM** (UNII: M28OL1HH48) | |
| **CROSPOVIDONE** (UNII: 2S7830E561) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |
| **ALUMINUM OXIDE** (UNII: LMI26O6933) | |

| | |
|---|---|
| **FD&C BLUE NO. 2** (UNII: L06K8R7DQK) | |
| **FERRIC OXIDE YELLOW** (UNII: EX438O2MRT) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A** (UNII: NX76LV5T8J) | |
| **MICA** (UNII: V8A1AW0880) | |
| **MICROCRYSTALLINE CELLULOSE** (UNII: OP1R32D61U) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **POLYVINYL ALCOHOL, UNSPECIFIED** (UNII: 532B59J990) | |
| **POVIDONE, UNSPECIFIED** (UNII: FZ989GH94E) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **SODIUM BICARBONATE** (UNII: 8MDF5V39QO) | |
| **STEARIC ACID** (UNII: 4ELV7Z65AP) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | blue | **Score** | no score |
| **Shape** | OVAL | **Size** | 19mm |
| **Flavor** | | **Imprint Code** | MVA |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | | 1 in 1 CARTON | | |
| **1** | | 10 in 1 BLISTER PACK; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product) | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph final | part341 | 08/01/2018 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph final | part341 | 12/15/2018 | 02/16/2025 |

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

Revised: 9/2023 RB Health (US) LLC