

**MUCINEX CHILDRENS DAY TIME MULTI-SYMPTOM COLD AND MUCINEX CHILDRENS NIGHT TIME MULTI-SYMPTOM COLD TRIPLE PACK- acetaminophen, diphenylhydramine hydrochloride, phenylephrine hydrochloride, dextromethorphan hydrobromide, and guaifenesin RB Health (US) LLC**

**Mucinex® Children's Day Time Multi-Symptom Cold and Mucinex® Children's Night Time Multi-Symptom Cold Triple Pack**

***Drug Facts***

<b><i>Active ingredients (in each 10 mL)</i></b>	<b><i>Purposes</i></b>
<b>Acetaminophen 325 mg</b>	<b>Pain reliever/fever reducer</b>
Diphenhydramine HCl 12.5 mg	Antihistamine/cough suppressant
Phenylephrine HCl 5 mg	Nasal decongestant

**Uses**

- temporarily relieves these common cold and flu symptoms
  - minor aches and pains
  - headache
  - sore throat
  - nasal congestion
  - runny nose
  - sneezing
  - cough
- controls cough to help your child get to sleep
- temporarily reduces fever

**Warnings**

**Liver warning**

This product contains acetaminophen. Severe liver damage may occur if your child takes:

- more than 5 doses in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen

**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.
- to make a child sleepy
- with any other product containing diphenhydramine, even one used on the skin
- in a child who is 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 child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

### **Ask a doctor before use if the child has**

- liver disease
- heart disease
- diabetes
- high blood pressure
- thyroid disease
- glaucoma
- a breathing problem such as chronic bronchitis
- persistent or chronic cough such as occurs with asthma
- cough that occurs with too much phlegm (mucus)

### **Ask a doctor or pharmacist before use if the child is**

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

### **When using this product**

- **do not use more than directed (see Overdose warning)**
- excitability may occur, especially in children
- marked drowsiness may occur
- sedatives and tranquilizers may increase drowsiness

### **Stop use and ask a doctor if**

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, or cough gets worse or lasts more than 5 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.

**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 even if you do not notice any signs or symptoms.

### **Directions**

- **this product does not contain directions or complete warnings for adult use**
- **do not give more than directed (see Overdose warning)**
- measure only with dosing cup provided
- do not use dosing cup with other products
- dose as follows or as directed by a doctor
- children 6 to under 12 years of age: 10 mL in dosing cup provided every 4 hours while symptoms last; do not give more than 5 doses in any 24-hour period
- children under 6 years of age: do not use

### **Other information**

- each 10 mL contains: **sodium 6 mg**
- store at 20-25°C (68-77°F)
- do not refrigerate

### **Inactive ingredients**

anhydrous citric acid, edetate disodium, FD&C blue no. 1, FD&C red no. 40, flavors, glycerin (soy), propyl gallate, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, trisodium citrate dihydrate <sup>1</sup>, xanthan gum

1 may contain this ingredient

### **Questions?**

**1-866-682-4639**

You may also report side effects to this phone number.

### **Drug Facts**

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<b>Active ingredients (in each 5 mL)</b>	<b>Purposes</b>
Dextromethorphan HBr 5 mg	Cough suppressant
Guaifenesin 100 mg	Expectorant
Phenylephrine HCl 2.5 mg	Nasal decongestant

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## Uses

- 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 intensity of coughing
  - the impulse to cough to help your child get to sleep
  - nasal congestion due to a cold
  - stuffy nose

## Warnings

**Do not use** in a child who is 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 child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

### **Ask a doctor before use if the child has**

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with asthma

### **When using this product do not use more than directed**

#### **Stop use and ask a doctor if**

- nervousness, dizziness, or sleeplessness occur
- symptoms do not get better within 7 days or occur with fever
- cough lasts more than 7 days, comes back, or occurs with fever, rash, or persistent headache. These could be signs of a serious condition.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

## Directions

- do not give more than 6 doses in any 24-hour period
- measure only with dosing cup provided
- do not use dosing cup with other products
- dose as follows or as directed by a doctor

Age	Dose
children 6 to under 12	10 ml every 4 hours

years of age	10 mL every 4 hours
children 4 to under 6 years of age	5 mL every 4 hours
children under 4 years of age	do not use

### Other information

- each 5 mL contains: **sodium 3 mg**
- store between 20-25°C (68-77°F)
- do not refrigerate

### Inactive ingredients

anhydrous citric acid, edetate disodium, FD&C red no. 40, flavors, glycerin (soy), propyl gallate, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, trisodium citrate dihydrate<sup>2</sup>, xanthan gum

2 may contain this ingredient

### 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 Mexico

### PRINCIPAL DISPLAY PANEL - Kit Carton

Pediatrician Recommended †

TRIPLE  
PACK

NDC 63824-944-34

READ ALL INFORMATION

Mucinex®  
Children's

DAY TIME  
MULTI-SYMPTOM  
COLD

Dextromethorphan HBr 5 mg - Cough Suppressant  
Guaifenesin 100 mg - Expectorant  
Phenylephrine HCl 2.5 mg - Nasal Decongestant

- Relieves Stuffy Nose

- Controls Cough
- Relieves Chest Congestion
- Breaks up Mucus

Ages  
4 +yrs

Very Berry  
Flavor Liquid

THREE - 4 FL OZ (118mL)

NIGHT TIME  
MULTI-SYMPTOM  
COLD

Acetaminophen 325 mg-Pain Reliever/Fever Reducer

Diphenhydramine HCl 12.5-Antihistamine/

Cough Suppressant

Phenylephrine HCl mg-Nasal Decongestant

- Relieves Stuffy Nose
- Controls Cough
- Relieves Runny Nose & Sneezing
- Relieves Fever & Sore Throat

Ages  
6 +yrs

Very Berry  
Flavor Liquid

TOTAL - 12 FL OZ (354mL)

Pediatrician Recommended!

**TRIPLE  
PACK**

NDC 63824-944-34

READ ALL INFORMATION



**DAY TIME  
MULTI-SYMPOM  
COLD**

Dextromethorphan HBr 5 mg - Cough Suppressant  
Guaifenesin 100 mg - Expectorant  
Phenylephrine HCl 2.5 mg - Nasal Decongestant

- ✓ Relieves Stuffy Nose
- ✓ Controls Cough
- ✓ Relieves Chest Congestion
- ✓ Breaks up Mucus

Ages 4+ yrs

Very Berry  
Flavor Liquid



THREE - 4 FL OZ (118mL)

**DAY TIME  
MULTI-SYMPOM  
COLD**

Dextromethorphan HBr 5 mg - Cough Suppressant  
Guaifenesin 100 mg - Expectorant  
Phenylephrine HCl 2.5 mg - Nasal Decongestant

- ✓ Relieves Stuffy Nose
- ✓ Controls Cough
- ✓ Relieves Chest Congestion
- ✓ Breaks up Mucus

Ages 4+ yrs

Very Berry  
Flavor Liquid



**NIGHT TIME  
MULTI-SYMPOM  
COLD**

Acetaminophen 325 mg - Pain Reliever/Fever Reducer  
Diphenhydramine HCl 12.5 mg - Antihistamine/  
Cough Suppressant  
Phenylephrine HCl 5 mg - Nasal Decongestant

- ✓ Relieves Stuffy Nose
- ✓ Controls Cough
- ✓ Relieves Runny Nose & Sneezing
- ✓ Relieves Fever & Sore Throat

Ages 6+ yrs

Very Berry  
Flavor Liquid



TOTAL - 12 FL OZ (354mL)

Print safe area

Night Time Multi-Symptom Cold - Ages 6+

**Drug Facts**

Active Ingredients (in each 10 mL)	Purposes
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
  - headache
  - nasal congestion
  - sneezing
  - minor aches and pains
  - sore throat
  - runny nose
  - cough
- controls cough to help your child get to sleep
- temporarily reduces fever

**Warnings**

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if your child takes:

- more than 5 doses in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen

**Allergy alert:** Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin redness
- 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.
- to make a child sleepy
- with any other product containing diphenhydramine, even one used on the skin
- in a child who is 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 child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

**Ask a doctor before use if the child has**

- liver disease
- high blood pressure
- a breathing problem such as chronic bronchitis
- persistent or chronic cough such as occurs with asthma
- cough that occurs with too much phlegm (mucus)
- heart disease
- thyroid disease
- diabetes
- glaucoma

**Ask a doctor or pharmacist before use if the child is**

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

Night Time Multi-Symptom Cold - Ages 6+ (cont'd)

**Drug Facts (continued)**

**When using this product**

- do not use more than directed (see Overdose warning)
- excitability may occur, especially in children
- marked drowsiness may occur
- sedatives and tranquilizers may increase drowsiness

**Stop use and ask a doctor if**

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, or cough gets worse or last more than 5 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.

**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 even if you do not notice any signs or symptoms.

**Directions**

- this product does not contain directions or complete warnings for adult use
- do not give more than directed (see Overdose warning)
- measure only with dosing cup provided
- do not use dosing cup with other products
- dose as follows or as directed by a doctor
- children 6 to under 12 years of age: 10 mL, in dosing cup provided every 4 hours while symptoms last; do not give more than 5 doses in any 24-hour period
- children under 6 years of age: do not use

**Other information**

- each 10 mL contains: sodium 6 mg
- store at 20-25°C (68-77°F)
- do not refrigerate

**Inactive ingredients** anhydrous citric acid, edetate disodium, FD&C blue no. 1, FD&C red no. 40, flavors, glycerin (soy), propyl gallate, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, trisodium citrate dihydrate, xanthan gum

Day Time Multi-Symptom Cold - Ages 4+

**Drug Facts**

Active ingredients (in each 5 mL)	Purposes
Dextromethorphan HBr 5 mg	Cough suppressant
Guaifenesin 100 mg	Expectorant
Phenylephrine HCl 2.5 mg	Nasal decongestant

**Uses**

- helps loosen phlegm (mucus) and thin bronchia 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 intensity of coughing
  - the impulse to cough to help your child get to sleep
  - nasal congestion due to a cold
  - stuffy nose

**Warnings**

**Do not use** in a child who is 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 child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

**Ask a doctor before use if the child has**

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with asthma

**When using this product do not use more than directed**

- Stop use and ask a doctor if
  - nervousness, dizziness, or sleeplessness occur
  - symptoms do not get better within 7 days or occur with fever
- cough lasts more than 7 days, comes back, or occurs with fever, rash, or persistent headache. These could be signs of a serious condition.

**Keep out of reach of children.** In case of overdose, get

Day Time Multi-Symptom Cold - Ages 4+ (cont'd)

**Drug Facts (continued)**

**Other information**

- each 5 mL contains: sodium 3 mg
- store at 20-25°C (68-77°F)
- do not refrigerate

**Inactive ingredients**

anhydrous citric acid, edetate disodium, FD&C red no. 40, flavors, glycerin (soy), propyl gallate, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, trisodium citrate dihydrate, xanthan gum

\* may contain this ingredient

**Questions? 1-866-MUCINEX (1-866-682-4639)**

You may also report side effects to this phone number.

As an OTC brand in the  
Children's Cough/Cold category  
(AlphaImpactRxProVoice Survey)

**DO NOT GIVE THE MUCINEX CHILDREN'S DAY TIME MULTI-SYMPOM COLD AND MUCINEX CHILDREN'S NIGHT TIME MULTI-SYMPOM COLD LIQUIDS AT THE SAME TIME.**

**ALWAYS WAIT AT LEAST 4 HOURS BEFORE GIVING ANOTHER DOSE OF MUCINEX CHILDREN'S LIQUID. DO NOT GIVE MORE THAN A TOTAL OF 5 DOSES IN ANY 24-HOUR PERIOD.**

Please visit our website [www.mucinex.com](http://www.mucinex.com)

**PARENTS:**

Learn about teen medicine abuse

[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)

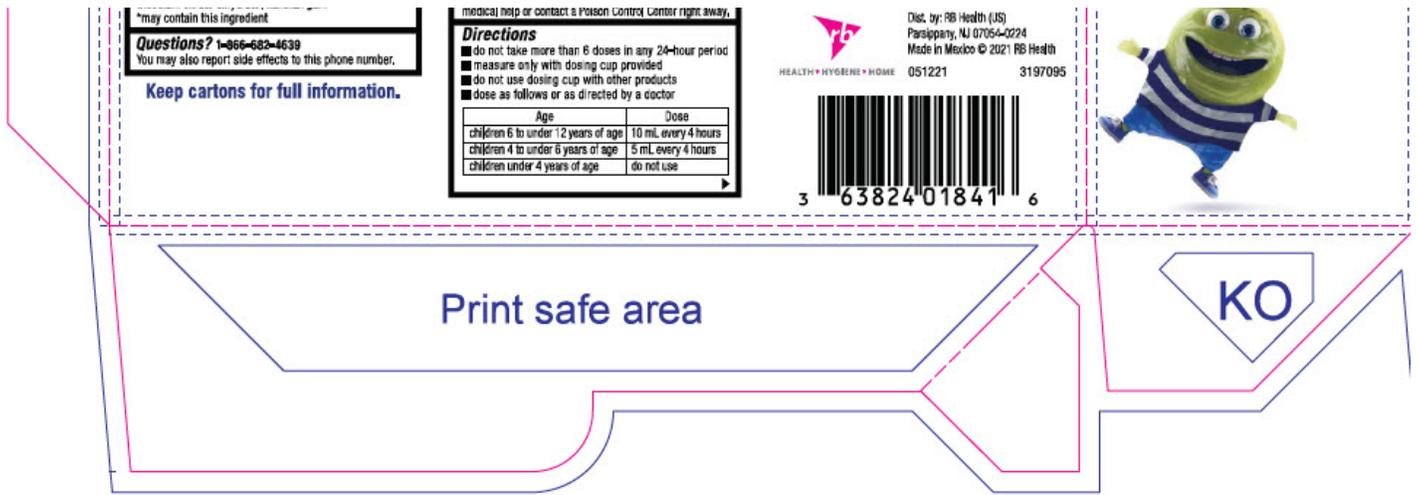
Pediatrician Recommended!

**TRIPLE  
PACK**



2X  
DAY TIME  
MULTI-SYMPOM  
COLD

1X  
NIGHT TIME  
MULTI-SYMPOM  
COLD



## MUCINEX CHILDRENS DAY TIME MULTI-SYMPTOM COLD AND MUCINEX CHILDRENS NIGHT TIME MULTI-SYMPTOM COLD TRIPLE PACK

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

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63824-944
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-944-34	1 in 1 CARTON	05/25/2022	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	2 BOTTLE	236 mL
Part 2	1 BOTTLE	118 mL

### Part 1 of 2

## MUCINEX CHILDRENS MULTI-SYMPTOM COLD

dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride suspension

### Product Information

<b>Item Code (Source)</b>	NDC:63824-949
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<b>Route of Administration</b>	ORAL
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## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 5 mL
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 5 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>PROPYL GALLATE</b> (UNII: 8D4SNN7V92)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>TRISODIUM CITRATE DIHYDRATE</b> (UNII: B22547B95K)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

## Product Characteristics

<b>Color</b>	red	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	BERRY	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-949-01	1 in 1 CARTON		
1		118 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	03/30/2018	

# MUCINEX CHILDRENS NIGHT TIME MULTI-SYMPTOM COLD

acetaminophen, diphenhydramine hydrochloride, and phenylephrine hydrochloride solution

## Product Information

**Item Code (Source)** NDC:63824-950

**Route of Administration** ORAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg in 10 mL
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	12.5 mg in 10 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 10 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>PROPYL GALLATE</b> (UNII: 8D4SNN7V92)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>TRISODIUM CITRATE DIHYDRATE</b> (UNII: B22547B95K)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

## Product Characteristics

<b>Color</b>	blue	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	BERRY	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-950-21	1 in 1 CARTON		
1		118 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	05/01/2018	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	05/25/2022	

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

Revised: 12/2024

RB Health (US) LLC