#### MUCINEX CHILDRENS FREEFROM MULTI-SYMPTOM COLD AND FLU NIGHTTIME- acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride, and triprolidine hydrochloride solution RB Health (US) LLC

\_\_\_\_\_

#### Mucinex® Children's FreeFrom Multi-Symptom Cold & Flu Nighttime

#### **Drug Facts**

Active ingredients (in each 10 mL)	Purpose	
Acetaminophen 325 mg	Pain reliever/fever reducer	
Dextromethorphan HBr 10 mg	Cough suppressant	
Phenylephrine HCl 5 mg	Nasal decongestant	
Triprolidine HCl 1.25 mg	Antihistamine	

### Uses

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

### Warnings

### Liver warning

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

- more than 1625 mg 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
- 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
- may cause marked drowsiness
- 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 4 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

ammonium glycyrrhizate, anhydrous citric acid, cochineal carmine, edetate disodium, flavors, glycerin (soy), maltodextrin, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum

### **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 - 118 mL Bottle Carton**

Pediatrician Recommended <sup>†</sup>

NIGHTTIME

NDC 63824-959-64

Mucinex® Children's

FREEFROM

MULTI-SYMPTOM COLD & FLU NIGHTTIME

ACETAMINOPHEN – PAIN RELIEVER/FEVER REDUCER DEXTROMETHORPHAN HBr – COUGH SUPPRESSANT PHENYLEPHRINE HCI – NASAL DECONGESTANT TRIPROLIDINE HCI – ANTIHISTAMINE

FREEFROM ARTIFICIAL FLAVORS, COLORS, & DYES • ALCOHOL & SUGAR

ELDERBERRY & CHERRY NATURAL FLAVOR

AGES 6+ YRS.

4 FL OZ (118 mL)

#### Drug Facts (continued)

#### When using this product

#### do not use more than directed (see Overdose warning)

- excitability may occur, especially in children
- may cause marked drowsiness
- 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 4 doses in any 24-hour period children under 6 years of age: do not use

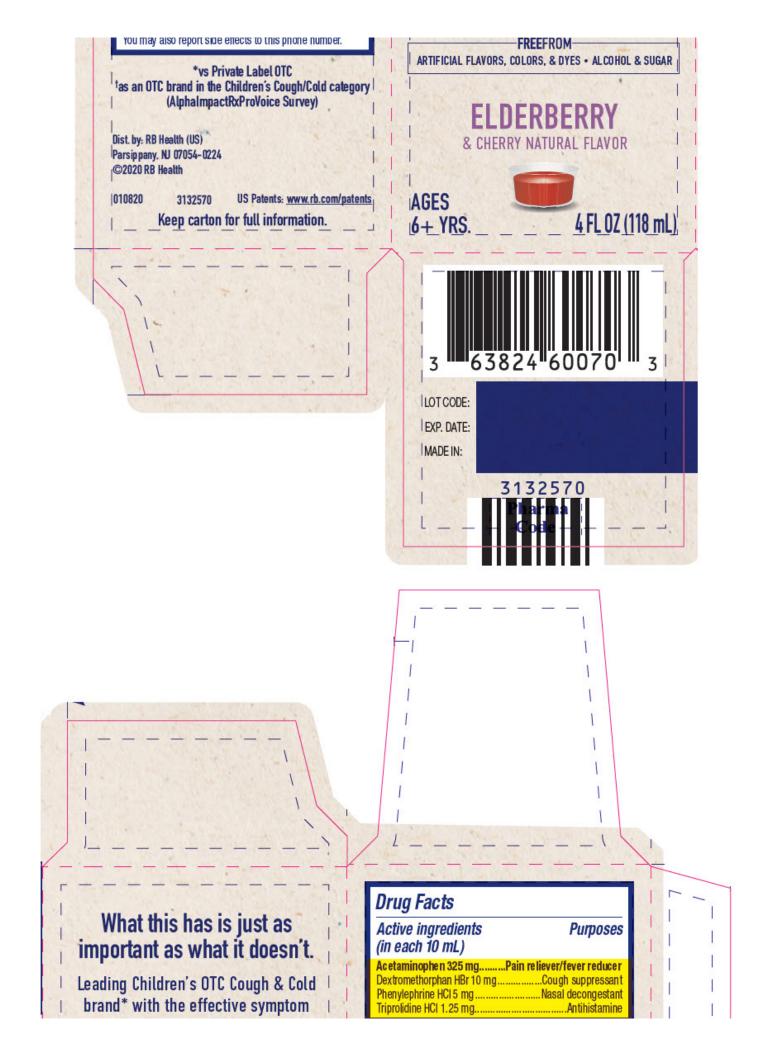
#### Other information

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

Inactive ingredients ammonium glycyrrhizate, anhydrous citric acid, cochineal carmine, edetate disodium, flavors, glycerin (soy), maltodextrin, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum

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





### relief you trust - FREEFROM the unwanted additives:

Caffeine Free · No Artificial Colors, | Dyes, or Flavors · Alcohol & Sugar Free No High Fructose Corn Syrup

# POWERFUL SYMPTOM RELIEF

- Nighttime Relief for a Better Morning
- ✓ Relieves Sore Throat & Stuffy Nose
- ✓ Controls Cough
- Relieves Runny Nose & Sneezing

DOSING CUP INCLUDED

ELDERBERRY

& CHERRY NATURAL FLAVOR

Learn about teen medicine abuse

www.StopMedicineAbuse.org

PAREN

✓ Reduces Fever

#### Uses

- temporarily relieves these common cold and flu symptoms:
   minor aches and pains
   headache
  - minor aches and pains
    sore throat
  - I runny nose
- nasal congestion
  sneezing
- stuffy nose
- temporarily reduces fever

controls cough to help your child get to sleep

#### Warnings

cough

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

more than 1625 mg in 24 hours, which is the maximum daily amount

with other drugs containing acetaminophen
 Allerov 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
- 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
  diabetes
- heart disease
  high blood pressure
- thyroid disease
- 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

Questions or comments? 1-866-Mucinex (1-866-682-4639) or www.mucinex.com

HEALTH . HYGIENE . HOME

# **MUCINEX CHILDRENS FREEFROM MULTI-SYMPTOM COLD AND FLU** NIGHTTIME

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride, and triprolidine hydrochloride solution

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:63824-959	
Route of Administration	ORAL				
Active Ingredient/Active Moiety					
Active mgreatent/Active	morecy				
Ingred	lient Name		Basis of Stre	ength	Strength
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)					
ACETAMINOPHEN (UNII: 36209ITL	9D) (ACETAMINOPHEN - UNI	I:362O9ITL9D)	ACETAMINOPHEN		325 mg in 10 mL
ACETAMINOPHEN (UNII: 36209ITL DEXTROMETHORPHAN HYDROBI (DEXTROMETHORPHAN - UNII:7355X	ROMIDE (UNII: 9D2RTI9KYH		ACETAMINOPHEN DEXTROMETHORPH HYDROBROMIDE	IAN	5
DEXTROMETHORPHAN HYDROB	ROMIDE (UNII: 9D2RTI9KYH 3ROTS)	)	DEXTROMETHORPH	IAN	in 10 mL 10 mg

TRIPROLIDINE HYDROCHLORIDE (UNII: YAN7R5L890) (TRIPROLIDINE -	TRIPROLIDINE
UNII:2L8T9S52QM)	HYDROCHLORIDE

Ingredient Name	Strength
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CARMINIC ACID (UNII: CID8Z8N95N)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics			
Color	red	Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			
Packaging			

#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:63824- 959-64	1 in 1 CARTON	06/01/2020				
1		118 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package					
M	Marketing Information						
	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
01	TC Monograph Dru	Ig M012	06/01/2020				

Labeler - RB Health (US) LLC (081049410)

Revised: 12/2024

RB Health (US) LLC