

MUCINEX CHILDRENS FREEFROM MULTI-SYMPTOM COLD AND FLU NIGHTTIME- acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride, and triprolidine hydrochloride solution
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.

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

Drug Facts

Active ingredients (in each 10 mL)	Purposes
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†

NIGHTTIME

NDC 63824-959-64

Mucinex®
Children's

FREEFROM

MULTI-SYMP TOM
COLD & FLU
NIGHTTIME

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

FREEFROM

ARTIFICIAL FLAVORS, COLORS, & DYES • ALCOHOL & SUGAR

ELDERBERRY
& CHERRY NATURAL FLAVOR

AGES

6+ YRS.

4 FL OZ (118 mL)

Tamper evident: Do not use if neckband on bottle cap is broken or missing.

Mucinex[®]
Children's

FREEFROM
MULTI-SYMPOM
COLD & FLU NIGHTTIME
ACETAMINOPHEN – PAIN RELIEVER/FEVER REDUCER
DEXTROMETHORPHAN HBr – COUGH SUPPRESSANT
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Drug Facts (continued)

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***vs Private Label OTC**
as an OTC brand in the Children's Cough/Cold category
(AlphaImpactRxProVoice Survey)

Dist. by: RB Health (US)
Parsippany, NJ 07054-0224
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010820 3132570 US Patents: www.rb.com/patents

Keep carton for full information.

FREEFROM

ARTIFICIAL FLAVORS, COLORS, & DYES • ALCOHOL & SUGAR

ELDERBERRY
& CHERRY NATURAL FLAVOR



AGES
6+ YRS.

4 FL OZ (118 mL)



3 63824 60070 3

LOT CODE:

EXP. DATE:

MADE IN:

3132570



Pharma
Code

**What this has is just as
important as what it doesn't.**

Leading Children's OTC Cough & Cold
brand* with the effective symptom

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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
- ✓ Reduces Fever

DOSING CUP INCLUDED



ELDERBERRY
& CHERRY NATURAL FLAVOR

PARENTS:

Learn about teen medicine abuse

www.StopMedicineAbuse.org



Questions or comments?
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or www.mucinex.com

HEALTH > HYGIENE > HOME

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MUCINEX CHILDRENS FREEFROM MULTI-SYMPATOM 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

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg in 10 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 10 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 10 mL
TRIPROLIDINE HYDROCHLORIDE (UNII: YAN7R5L890) (TRIPROLIDINE - UNII:2L8T9S52QM)	TRIPROLIDINE HYDROCHLORIDE	1.25 mg in 10 mL

Inactive Ingredients

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		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	06/01/2020	

Labeler - RB Health (US) LLC (081049410)

Revised: 3/2021

RB Health (US) LLC