

CHILDRENS MUCINEX MULTI SYMPTOM COLD AND CHILDRENS MUCINEX NIGHT TIME MULTI SYMPTOM COLD- acetaminophen, dextromethorphan hydrobromide, diphenhydramine hydrochloride, guaifenesin, and phenylephrine hydrochloride
RB Health (US)

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.

Children's Mucinex® Multi Symptom Cold and Children's Mucinex® Night Time Multi Symptom Cold

Day Time Multi-Symptom Cold – Age 4+

Drug Facts

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

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

- your child gets nervous, dizzy or sleepless
- 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 illness.

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

Directions

- do not take 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
- mL = milliliter

Age	Dose
children 6 years to under 12 years	10 mL every 4 hours
children 4 years to under 6 years	5 mL every 4 hours
children under 4 years	do not use

Other information

- each 5 mL contains: **sodium 3 mg**
- tamper evident: do not use if neckband on bottle cap is broken or missing
- store between 20-25°C (68-77°F)
- do not refrigerate
- dosing cup provided

Inactive ingredients

anhydrous citric acid, edetate disodium, FD&C Red #40, flavors, glycerin, propylene glycol, propyl gallate, purified water, sodium benzoate, sorbitol, sucralose, trisodium citrate dihydrate¹, xanthan gum

¹ may contain this ingredient

Questions?

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

You may also report side effects to this phone number.

Night Time Multi-Symptom Cold – Age 6+

Drug Facts

<i>Active ingredients (in each 10 mL)</i>	<i>Purposes</i>
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:
 - 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

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 drug 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 your 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 your 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 for adults as well as for children 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)**
- if needed, repeat dose every 4 hours while symptoms last
- do not give more than 5 days unless directed by a doctor
- measure only with dosing cup provided
- do not use dosing cup with other products
- dose as follows or as directed by a doctor
- mL = milliliter
- children 6 to under 12 years of age: 10 mL in dosing cup provided every 4 hours; 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 between 20-25°C (68-77°F)
- dosing cup provided
- do not refrigerate

Inactive ingredients

anhydrous citric acid, edetate disodium, FD&C Blue #1, FD&C Red #40, flavors, glycerin, propylene glycol, propyl gallate, purified water, sodium benzoate, sorbitol, sucralose, trisodium citrate dihydrate², 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: Reckitt Benckiser, Parsippany, NJ 07054-0224

Made in England

PRINCIPAL DISPLAY PANEL - Kit Carton

VALUE

PACK

NDC 63824-287-22

**Children's
Mucinex®**

DAY TIME

**Multi-Symptom
Cold**

Cough Suppressant
Expectorant
Nasal Decongestant

Dextromethorphan HBr 5 mg
Guaifenesin 100 mg
Phenylephrine HCl 2.5 mg

- ☐ **Stuffy Nose**
- ☐ **Cough**
- ☐ **Chest Congestion**
- ☐ **Breaks up Mucus**

Age 4+

**Very Berry
Flavor Liquid**

4 FL OZ (118 mL)

NIGHT TIME

**Multi-Symptom
Cold**

Pain Reliever/Fever Reducer
Antihistamine/Cough Suppressant
Nasal Decongestant

Acetaminophen 325 mg
Diphenhydramine HCl 12.5 mg
Phenylephrine HCl 5 mg

- ☐ **Stuffy Nose**
- ☐ **Cough**
- ☐ **Runny Nose & Sneezing**
- ☐ **Fever & Sore Throat**

Age 6+

**Mixed Berry
Flavor Liquid**

4 FL OZ (118 mL)

8 FL OZ (236 mL) TOTAL

**VALUE
PACK**

NDC 63824-287-22

Children's Mucinex®



DAY TIME

Multi-Symptom Cold

Cough Suppressant
Expectorant
Nasal Decongestant

Dextromethorphan HBr 5 mg
Guaifenesin 100 mg
Phenylephrine HCl 2.5 mg

- ✓ **Stuffy Nose**
- ✓ **Cough**
- ✓ **Chest Congestion**
- ✓ **Breaks up Mucus**

Age **4+**

**Very Berry
Flavor Liquid**



4 FL OZ (118 mL)



NIGHT TIME

Multi-Symptom Cold

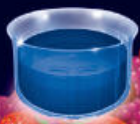
Pain Reliever/Fever Reducer
Antihistamine/Cough Suppressant
Nasal Decongestant

Acetaminophen 325 mg
Diphenhydramine HCl 12.5 mg
Phenylephrine HCl 5 mg

- ✓ **Stuffy Nose**
- ✓ **Cough**
- ✓ **Runny Nose & Sneezing**
- ✓ **Fever & Sore Throat**

Age **6+**

**Mixed Berry
Flavor Liquid**



4 FL OZ (118 mL)

PRINT SAFE AREA

Day Time Multi-Symptom Cold – Age 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 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

- your child gets nervous, dizzy or sleepless
- 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 illness.

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

Directions

- do not take 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
- mL = milliliter

Age	Dose
children 6 years to under 12 years	10 mL every 4 hours
children 4 years to under 6 years	5 mL every 4 hours
children under 4 years	do not use

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

Drug Facts (continued)

Other information

- each 5 mL contains: sodium 3 mg
- tamper evident: do not use if neckband on bottle cap is broken or missing
- store between 20-25°C (68-77°F)
- do not refrigerate

Night Time Multi-Symptom Cold – Age 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

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

Drug Facts (continued)

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

- dosing cup provided

Inactive ingredients anhydrous citric acid, edetate disodium, FD&C Red #40, flavors, glycerin, propylene glycol, propyl gallate, 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.

DO NOT GIVE THE FIRST DOSE OF NIGHT TIME MULTI-SYMPTOM COLD SOONER THAN 4 HOURS AFTER THE LAST DOSE OF DAY TIME MULTI-SYMPTOM COLD UNLESS DIRECTED BY A DOCTOR. DO NOT GIVE BOTH PRODUCTS AT THE SAME TIME OR GIVE MORE THAN 5 DOSES IN TOTAL IN ANY 24 HOUR PERIOD.

PARENTS:
Learn about teen medicine abuse
www.StopMedicineAbuse.org

3-63824-90994-3

Uses

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

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
- 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 drug 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 your child has

- liver disease
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- 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 your 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 ▶

- 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 for adults as well as for children even if you do not notice any signs or symptoms.

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Other information

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

Inactive ingredients anhydrous citric acid, edetate disodium, FD&C Blue #1, FD&C Red #40, flavors, glycerin, propylene glycol, propyl gallate, 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.

Keep cartons for full directions for use.



Dist. by: Reckitt Benckiser, Parsippany, NJ 07054-0224
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CHILDRENS MUCINEX MULTI SYMPTOM COLD AND CHILDRENS MUCINEX NIGHT TIME MULTI SYMPTOM COLD

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63824-287
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-287-22	1 in 1 CARTON	04/01/2014	

Quantity of Parts

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

Part 1 of 2

CHILDRENS MUCINEX MULTI-SYMPTOM COLD

dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride solution

Product Information

Route of Administration	ORAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Dextromethorphan Hydrobromide (UNII: 9D2RT9KYH) (Dextromethorphan - UNII:7355X3ROTS)	Dextromethorphan Hydrobromide	5 mg in 5 mL
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	100 mg in 5 mL
Phenylephrine Hydrochloride (UNII: 04JA59TNSJ) (Phenylephrine - UNII:1WS297W6MV)	Phenylephrine Hydrochloride	2.5 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
anhydrous citric acid (UNII: XF417D3PSL)	
edetate disodium (UNII: 7FLD91C86K)	
FD&C Red No. 40 (UNII: WZB9127XOA)	
glycerin (UNII: PDC6A3C0OX)	
propylene glycol (UNII: 6DC9Q167V3)	
propyl gallate (UNII: 8D4SNN7V92)	
water (UNII: 059QF0KO0R)	
sodium benzoate (UNII: OJ245FE5EU)	
sorbitol (UNII: 506T60A25R)	
sucralose (UNII: 96K6UQ3ZD4)	
trisodium citrate dihydrate (UNII: B22547B95K)	
xanthan gum (UNII: TTV12P4NEE)	

Product Characteristics

Color	PINK	Score	
Shape		Size	

Flavor	BERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		118 mL in 1 BOTTLE; 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	07/17/2012	

Part 2 of 2

CHILDRENS MUCINEX NIGHT TIME MULTI-SYMPTOM COLD

acetaminophen, diphenhydramine hydrochloride, and phenylephrine hydrochloride solution

Product Information

Route of Administration	ORAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Acetaminophen (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)	Acetaminophen	325 mg in 10 mL
Diphenhydramine Hydrochloride (UNII: TC2D6JAD40) (Diphenhydramine - UNII:8GTS82S83M)	Diphenhydramine Hydrochloride	12.5 mg in 10 mL
Phenylephrine Hydrochloride (UNII: 04JA59TNSJ) (Phenylephrine - UNII:1WS297W6MV)	Phenylephrine Hydrochloride	5 mg in 10 mL

Inactive Ingredients

Ingredient Name	Strength
anhydrous citric acid (UNII: XF417D3PSL)	
edetate disodium (UNII: 7FLD91C86K)	
FD&C Blue No. 1 (UNII: H3R47K3TBD)	
FD&C Red No. 40 (UNII: WZB9127XOA)	
glycerin (UNII: PDC6A3C0OX)	
propylene glycol (UNII: 6DC9Q167V3)	
propyl gallate (UNII: 8D4SNN7V92)	
water (UNII: 059QF0KO0R)	
sodium benzoate (UNII: OJ245FE5EU)	
sorbitol (UNII: 506T60A25R)	

sucralose (UNII: 96K6UQ3ZD4)	
trisodium citrate dihydrate (UNII: B22547B95K)	
xanthan gum (UNII: TTV12P4NEE)	

Product Characteristics

Color	BLUE	Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		118 mL in 1 BOTTLE; 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	03/25/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	04/01/2014	

Labeler - RB Health (US) (081049410)