

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

Mucinex® Children's

Day Time Multi-Symptom Cold and Night Time Multi-Symptom Cold

Day Time Multi-Symptom Cold - Ages 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

- 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 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 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 ¹, 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 - 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:
 - 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 ², 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 †

VALUE

PACK

READ ALL INFORMATION

NDC 63824-955-74

MUCINEX®

Children's

DAY TIME

MULTI-SYMP TOM

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

4 FL OZ (118 mL)

NIGHT TIME

MULTI-SYMPTOM

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

4 FL OZ (118 mL)

8 FL OZ (236 mL) TOTAL

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)
- sensitivity may occur, especially in children
- marked drowsiness may occur
- sedatives and tranquilizers may increase drowsiness

Stop use and ask a doctor if

- severe dizziness, or sleeplessness occur
- fever, 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

do not give more than directed (see Overdose warning)

- measure only with dosing cup provided
- do not use dosing cup with other products
- do 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 (veg), propyl galate, propylene glycol, purified water, sodium benzoate, sorbitol, sucrose, tri-sodium citrate dihydrate, xanthan gum

Questions? 1-866-MUCINEX (1-866-682-4639)
You may also report side effects to this phone number.

Keep cartons for full information.

Day Time Multi-Symptom Cold – Ages 4+

Drug Facts

Active ingredients (in each 5 mL)

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

Purposes

- relieves cough
- relieves chest congestion
- relieves nasal congestion
- relieves fever

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 related irritants
- the irritation 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
- hypertensive 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

- irritation, 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 5 doses in any 24-hour period

- measure only with dosing cup provided
- do not use dosing cup with other products
- do as follows or as directed by a doctor

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

Questions? 1-866-MUCINEX (1-866-682-4639)
You may also report side effects to this phone number.

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 (veg), propyl galate, propylene glycol, purified water, sodium benzoate, sorbitol, sucrose, tri-sodium citrate dihydrate, xanthan gum

Questions? 1-866-MUCINEX (1-866-682-4639)
You may also report side effects to this phone number.

is an OTC brand in the Children's Cough/Cold category (AlphaImpact's ProVoice Survey)

DO NOT GIVE THE MUCINEX CHILDREN'S DAY TIME MULTI-SYMP TOM COLD AND MUCINEX CHILDREN'S NIGHT TIME MULTI-SYMP TOM 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

PARENTS:
Learn about the risks of drug abuse
www.StopMedicineAbuse.org

Dist. by: RB Health (US)
Paramaribo, NY 07654-0224
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011419 8351908

Pediatrician Recommended

VALUE PACK

READ ALL INFORMATION

NDC 63824-955-74

Mucinex Children's

DAY TIME MULTI-SYMP TOM COLD

NIGHT TIME MULTI-SYMP TOM COLD

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

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 Chest Congestion
Breaks up Mucus

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

Very Berry Flavor Liquid (Ages 4+ yrs)

Very Berry Flavor Liquid (Ages 6+ yrs)

4 FL OZ (118 mL) 8 FL OZ (236 mL) TOTAL 4 FL OZ (118 mL)

Night Time Multi-Symptom Cold – Ages 6+

Drug Facts

Active ingredients (in each 10 mL)

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

Purposes

- relieves cough
- relieves chest congestion
- relieves nasal congestion
- relieves fever

Uses

- temporarily relieves these symptoms on cold and the symptoms
- minor aches and pains
- headache
- runny nose
- nasal congestion
- stuffy nose
- sneezing
- cough
- controls cough to help your child get to sleep
- temporarily relieves fever

Warnings

Live warnings: 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: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin redness
- hives
- itch
- 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
- high blood pressure
- hypertensive disease
- glaucoma
- is 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

MUCINEX CHILDREN'S DAY TIME MULTI-SYMP TOM COLD AND NIGHT TIME MULTI-SYMP TOM COLD

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

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63824-955

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-955-74	1 in 1 CARTON	01/21/2019	

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

MUCINEX CHILDREN'S MULTI-SYMP TOM COLD

dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride suspension

Product Information	
Item Code (Source)	NDC:63824-949

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RT19KYH) (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)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
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	red	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 Drug	M012	01/21/2019	

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
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)	
PROPYL GALLATE (UNII: 8D45NN7V92)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
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 Drug	M012	01/21/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	01/21/2019	

Labeler - RB Health (US) LLC (081049410)

Revised: 12/2024

RB Health (US) LLC