

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

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

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-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

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

Stop use and ask a doctor if:

- irritability, dizziness, or sleeplessness occur
- stuffy nose, 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)
- 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, aspartame, FD&C Blue No. 1, FD&C Red No. 40, flavors, glycerin, propyl gallate, propylene glycol, purified water, sodium benzoate, sorbitol, sucrose, titanium dioxide, 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 nasal congestion
- relieves chest congestion
- relieves fever
- relieves sore throat

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 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 neurological 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 using 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:

- irritability, 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

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, aspartame, FD&C Red No. 40, flavors, glycerin (syrup), propyl gallate, propylene glycol, purified water, sodium benzoate, sorbitol, sucrose, titanium dioxide, 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 (AlphaImpactXProVoice Survey)

DO NOT GIVE THE MUCINEX CHILDREN'S DAY TIME MULTI-SYMPTOM COLD AND MUCINEX CHILDREN'S NIGHT TIME MULTI-SYMPTOM 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 how to read the above.

www.StopMedicineAbuse.org

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Passaic, NJ 07654-0224
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Pediatrician Recommended

VALUE PACK

READ ALL INFORMATION

NDC 63824-955-74

Mucinex Children's

DAY TIME MULTI-SYMPTOM COLD

NIGHT 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

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

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)

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

Purposes

- temporarily relieves these common cold and flu symptoms:

 - runny nose
 - stuffy nose
 - nasal congestion
 - throat soreness
 - fever
 - aches and pains
 - headache
 - sore throat
 - skin redness
 - blister
 - itch

Uses

- temporarily relieves these common cold and flu symptoms:

 - runny nose
 - stuffy nose
 - nasal congestion
 - throat soreness
 - fever
 - aches and pains
 - headache
 - sore throat
 - skin redness
 - blister
 - itch

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
- blister
- itch
- 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, tinnitus, 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

is a child who is taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or neurological 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
- 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

MUCINEX CHILDRENS DAY TIME MULTI-SYMPTOM COLD AND NIGHT TIME MULTI-SYMPTOM 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 CHILDRENS MULTI-SYMPTOM 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: 9D2RTI9KYH) (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 final	part341	01/21/2019	

Part 2 of 2

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: 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	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	01/21/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/21/2019	

Labeler - RB Health (US) LLC (081049410)

Revised: 5/2022

RB Health (US) LLC