

**CHILDRENS DELSYM COUGH PLUS CHEST CONGESTION DM AND DELSYM COUGH PLUS COLD NIGHT TIME- acetaminophen, dextromethorphan hydrobromide, diphenhydramine hydrochloride, guaifenesin, and phenylephrine 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.*

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**Children's Delsym<sup>®</sup> Cough Plus<sup>®</sup> Chest Congestion DM and Delsym Cough Plus<sup>®</sup> Cold Night Time**

**COUGH+ CHEST CONGESTION DM - AGES 4+**

***Drug Facts***

<b><i>Active ingredients (in each 5 mL)</i></b>	<b><i>Purposes</i></b>
Dextromethorphan HBr 5 mg	Cough suppressant
Guaifenesin 100 mg	Expectorant

**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

**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**

- persistent or chronic cough such as occurs with asthma
- cough that occurs with too much phlegm (mucus)

**When using this product do not use more than directed**

**Stop use and ask a doctor if**

- cough lasts more than 7 days, 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.

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 (year)	Dose (mL)
children 6 to under 12 years of age	5 mL - 10 mL every 4 hours
children 4 to under 6 years of age	2.5 mL - 5 mL every 4 hours
children under 4 years of age	do not use

### Other information

- each 5 mL contains: **sodium 3 mg**
- store between 20-25°C (68-77°F)
- do not refrigerate

### Inactive ingredients

anhydrous citric acid, edetate disodium, FD&C red no. 40, flavors, glycerin, propyl gallate, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, trisodium citrate dihydrate <sup>1</sup>, xanthan gum

1 may contain this ingredient

### COUGH+ COLD NIGHT TIME - AGES 6+

### Drug Facts

<b>Active ingredients (in each 10 mL)</b>		<b>Purpose</b>
<b>Acetaminophen 325 mg</b>		<b>Pain reliever/fever reducer</b>
Diphenhydramine HCl 12.5 mg	Antihistamine/cough suppressant	
Phenylephrine HCl 5 mg	Nasal decongestant	

## **Uses**

- temporarily relieves these common cold and flu symptoms:
  - cough
  - nasal congestion
  - minor aches and pains
  - sore throat
  - headache
  - runny nose
  - sneezing
- 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 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 the 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; not to exceed 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)
- do not refrigerate

### **Inactive ingredients**

anhydrous citric acid, edetate disodium, FD&C blue no. 1, FD&C red no. 40, flavors, glycerin, propyl gallate, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, trisodium citrate dihydrate <sup>2</sup>, xanthan gum

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2 may contain this ingredient

### **Questions?**

**1-866-682-4639**

**You may also report side effects to this phone number.**

Dist. by: Reckitt Benckiser

Parsippany, NJ 07054-0224

### **PRINCIPAL DISPLAY PANEL - Kit Carton**

NDC 63824-218-22

DAY

NIGHT

COMBO

PACK

Children's

Delsym<sup>®</sup>

COUGH+<sup>®</sup>

Chest Congestion

DM

Dextromethorphan HBr (Cough Suppressant)

Guaifenesin (Expectorant)

- Relieves Cough
- Relieves Chest

Congestion

- Thins &

Loosens

Mucus

Cherry Flavor

For Ages

4

years+

COUGH+ <sup>®</sup>Cold

Night Time

Acetaminophen (Pain Reliever/Fever Reducer)

Diphenhydramine HCl (Antihistamine/Cough Suppressant)

Phenylephrine HCl (Nasal Decongestant)

- Relieves Cough
- Relieves

Stuffy Nose

- Relieves

Sore Throat

- Reduces Fever

Berry Flavor

For Ages

6

years+

TWO - 4 fl oz (118 mL) bottles TOTAL - 8 fl oz (236 mL)

COUGH+ COLD NIGHT TIME – 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:

- irritation, 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, propyl gallate, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, triiodine citrate diphosphate, xanthan gum

may contain this ingredient

Keep cartons for full information.

COUGH+ CHEST CONGESTION DM – AGES 4+

Drug Facts

Active ingredients (in each 5 mL)

Dextromethorphan HBr 5 mg..... Cough suppressant

Guaifenesin 100 mg.....Expectorant

Purposes

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageway 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

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageway 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

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:
- persistent or chronic cough such as occurs with asthma
- cough that occurs with too much phlegm (mucus)

When using this product do not use more than directed

Stop use and ask a doctor if:

- 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 and contact a Poison Control Center right away.

Directions

- this product does not contain directions or complete warnings for adult use
- 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
- children 6 years to under 12 years of age: 5 mL – 10 mL, every 4 hours
- children 4 years to under 6 years of age: 2.5 mL – 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 blue no. 1, FD&C red no. 40, flavors, glycerin, propyl gallate, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, triiodine citrate diphosphate, xanthan gum

may contain this ingredient

COUGH+ CHEST CONGESTION DM – AGES 4+ (cont'd)

Drug Facts (continued)

Inactive ingredients

anhydrous citric acid, edetate disodium, FD&C red no. 40, flavors, glycerin, propyl gallate, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, triiodine citrate diphosphate, xanthan gum

may contain this ingredient

Questions? 1-800-822-4239

You may also report side effects to this phone number.

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

Do not give the Children's Delsym Cough+ Chest Congestion DM and Children's Delsym Cough+ Cold Night Time liquids at the same time.

Always wait at least 4 hours before giving another dose of Children's Delsym Cough + Cold Night Time liquid. Do not give more than a total of 5 doses in any 24-hour period.

PARENTS:

Learn about teen medicine abuse

[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)

Please visit our website

[www.delsym.com](http://www.delsym.com)

Dist. by: RB Health (US)

Paracympany, NJ 07054-0224

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US Patients: [www.rb.com/patients](http://www.rb.com/patients)

Day

COMBO PACK

AGES 4+

COUGH+ CHEST CONGESTION DM

Dextromethorphan HBr (Cough Suppressant)

Guaifenesin (Expectorant)

- Relieves Cough & Chest Congestion
- Thins and Loosens Mucus

Night

COMBO PACK

AGES 6+

COUGH+ COLD NIGHT TIME

Acetaminophen (Pain Reliever/Fever Reducer)

Diphenhydramine HCl (Antihistamine/Cough Suppressant)

Phenylephrine HCl (Nasal Decongestant)

- Relieves Cough, Stuffy Nose & Sore Throat
- Reduces Fever

cherry

Flavored Liquid

Two - 4 fl oz (118 mL) bottles TOTAL – 8 fl oz (236 mL)

berry

Flavored Liquid

COUGH+ COLD NIGHT TIME – 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

Uses

- temporarily relieves these common cold and flu symptoms:
- cough
- nasal congestion
- minor aches and pains
- sore throat
- headache
- runny nose
- irritating
- 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 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
- hives
- rash
- If a skin reaction occurs, stop use and seek medical help right away.

Same 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 sleep
- 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
- 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

CHILDRENS DELSYM COUGH PLUS CHEST CONGESTION DM AND DELSYM COUGH PLUS COLD NIGHT TIME

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

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63824-218

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-218-22	1 in 1 CARTON	07/01/2017	

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 DELSYM COUGH PLUS CHEST CONGESTION DM

dextromethorphan hydrobromide and guaifenesin solution

Product Information	
Item Code (Source)	NDC:63824-214

<b>Route of Administration</b>	ORAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 5 mL
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PROPYL GALLATE</b> (UNII: 8D4SNN7V92)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>TRISODIUM CITRATE DIHYDRATE</b> (UNII: B22547B95K)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

Product Characteristics

<b>Color</b>	red	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY	<b>Imprint Code</b>	
<b>Contains</b>			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/08/2017	



**CHILDRENS DELSYM COUGH PLUS COLD NIGHT TIME**

acetaminophen, diphenhydramine hydrochloride, and phenylephrine hydrochloride solution

**Product Information**

**Item Code (Source)** NDC:63824-212

**Route of Administration** ORAL

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg in 10 mL
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	12.5 mg in 10 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 10 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PROPYL GALLATE</b> (UNII: 8D4SNN7V92)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>TRISODIUM CITRATE DIHYDRATE</b> (UNII: B22547B95K)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

**Product Characteristics**

<b>Color</b>	blue	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	BERRY	<b>Imprint Code</b>	
<b>Contains</b>			

**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	07/13/2017	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/01/2017	

**Labeler -** RB Health (US) LLC (081049410)

Revised: 2/2023

RB Health (US) LLC