

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

Children's Delsym[®] Cough Plus[®] Chest Congestion DM and Delsym Cough Plus[®] Cold Night Time

COUGH+ CHEST CONGESTION DM - 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

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 ¹, xanthan gum

¹ may contain this ingredient

COUGH+ COLD NIGHT TIME - AGES 6+

Drug Facts

Active ingredients (in each 10 mL)	Purpose
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
- 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 dihydrate², xanthan gum

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[®]

COUGH+[®]

Chest Congestion

DM

Dextromethorphan HBr (Cough Suppressant)

Guaifenesin (Expectorant)

- Relieves Cough
- Relieves Chest

Congestion

- Thins &

Loosens

Mucus

Cherry Flavor

For Ages

4

years+

COUGH+ [®]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)

Warnings:

- do not use more than directed (see Overdose warning)
- 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

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
- 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, propyl galate, polyethylene 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

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 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

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
- do as follows or as directed by a doctor

Age (year)	Dose (mL)
children 6 years to under 12 years of age	5 mL – 10 mL (over) 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

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 galate, polyethylene glycol, purified water, sodium benzoate, sorbitol, sucralose, triiodine citrate diphosphate, xanthan gum

may contain this ingredient

Questions? 1-866-822-4639

You may also report side effects to this phone number.

Tamper evident: Do not use if knockdown 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

Please visit our website
www.delsym.com
Dist. by: RB Health (US)
Partyspany, NJ 07054-0224
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US Patents: www.rb.com/patents

Day **Night**

children's Delsym

COMBO PACK

AGES 4+ **AGES 6+**

COUGH+ CHEST CONGESTION DM **COUGH+ COLD NIGHT TIME**

Dextromethorphan HBr (Cough Suppressant)
Guaifenesin (Expectorant)

Acetaminophen (Pain Reliever/Fever Reducer)
Diphenhydramine HCl (Antihistamine/Cough Suppressant)
Phenylephrine HCl (Nasal Decongestant)

- Relieves Cough & Chest Congestion
- Thins and Loosens Mucus
- Relieves Cough, Stuffy Nose & Sore Throat
- Reduces Fever

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

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

Purposes

Uses

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

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

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin redness
- hives
- rash

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
- 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

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

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
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	CHERRY	Imprint Code	
Contains			

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 Drug	M012	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
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)	
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 Drug	M012	07/13/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	07/01/2017	

Labeler - RB Health (US) LLC (081049410)

Revised: 12/2024

RB Health (US) LLC