

**CHILDRENS DELSYM COUGH PLUS COLD NIGHT TIME- acetaminophen, diphenhydramine hydrochloride, and phenylephrine hydrochloride solution
RB Health (US) LLC**

Children's Delsym®

Cough Plus Cold Night Time

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:
 - 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 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, trisodium citrate dihydrate ¹, xanthan gum

¹ may contain this ingredient

Questions?

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 England

PRINCIPAL DISPLAY PANEL - 118 mL Bottle Carton

NDC 63824-212-64

Ages 6 Years+

Children's

Delsym®

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

4 fl oz (118 mL)

**COUGH+
COLD
NIGHTTIME**

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:
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
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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.
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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

Drug Facts (continued)
When using this product
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*may contain this ingredient

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Keep carton for full information.

children's Delsym
NDC 63824-212-64
Night
AGES 6+

**COUGH+
COLD
NIGHTTIME**

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

Relieves Cough, Stuffy Nose & Sore Throat
Reduces Fever

berry Flavored Liquid 4 fl oz (118 mL)

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1.00

1

1.00

Please visit our website www.delsym.com

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

Dosing cup included

Dist. by: RB Health (US), Parsippany, NJ 07054-0224
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CHILDRENS DELSYM COUGH PLUS COLD NIGHT TIME

acetaminophen, diphenhydramine hydrochloride, and phenylephrine hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	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)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
WATER (UNII: 059QF0K00R)	
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	NDC:63824-212-66	180 mL in 1 BOTTLE; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)	03/18/2013	08/31/2019
2	NDC:63824-212-64	1 in 1 CARTON	06/09/2017	

2

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	03/18/2013	

Labeler - RB Health (US) LLC (081049410)

Revised: 12/2024

RB Health (US) LLC