

# CVS CHILDRENS COLD PLUS COUGH PLUS RUNNY NOSE- acetaminophen, chlorpheniramine maleate, and dextromethorphan hydrobromide suspension CVS

*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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## CVS Health Children's COLD + Cough & Runny Nose

### Drug Facts

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#### Active ingredients (in each 5 Purposes mL)

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Acetaminophen 160 mg	Pain reliever/fever reducer
Chlorpheniramine maleate 1 mg	Antihistamine
Dextromethorphan HBr 5 mg	Cough suppressant

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### Uses

- temporarily relieves the following cold/flu symptoms:
  - minor aches and pains
  - headache
  - sore throat
  - sneezing and runny nose
  - cough
- 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
- 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.
- if your child has ever had an allergic reaction to this product or any of its ingredients

### **Ask a doctor before use if your child has**

- liver disease
- a breathing problem such as chronic bronchitis
- glaucoma
- 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 your child is**

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

### **When using this product**

- **do not exceed recommended dose (see overdose warning)**
- marked drowsiness may occur
- sedatives and tranquilizers may increase drowsiness
- excitability may occur, especially in children

### **Stop use and ask a doctor if**

- pain or cough gets worse or lasts more than 5 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present
- cough comes back or occurs with rash or headache that lasts

These could be signs of a serious condition.

**Keep out of reach of children.**

### **Overdose warning**

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) Quick medical attention is critical for adults as well as for children 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)**
- **shake well before using**
- mL = milliliter
- find right dose on chart below. If possible, use weight to dose; otherwise, use age.
- remove the child protective cap and squeeze your child's dose into the dosing cup
- repeat dose every 4 hours, while symptoms last
- do not give more than 5 times in 24 hours

<b>Weight (lb)</b>	<b>Age (yr)</b>	<b>Dose (mL)</b>
under 36	under 4 years	do not use
36-47	4 to 5 years	do not use unless directed by a doctor
48-95	6 to 11 years	10 mL

**Attention:** use only enclosed dosing cup specifically designed for use with this product. Do not use any other dosing device.

## Other information

- **each 5 mL contains:** sodium 3 mg
- store at room temperature

**TAMPER-EVIDENT: DO NOT USE IF PRINTED INNER SEAL UNDER CAP IS TORN OR MISSING**

## Inactive ingredients

anhydrous citric acid, carboxymethylcellulose sodium, D&C Red No. 33, edetate disodium, FD&C Blue No. 1, FD&C Red No. 40, flavors, glycerin, microcrystalline cellulose, propyl gallate, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucrose, xanthan gum

## Questions or comments?

**1-866-467-2748**

## PRINCIPAL DISPLAY PANEL

NDC 69842-792-04

CVS Health®

**Compare to the active ingredients in Children's Tylenol® Cold + Cough + Runny Nose\***

**Suspension Liquid**

**Children's Cough & Runny Nose**

**ACETAMINOPHEN,**

Pain Reliever-Fever Reducer

**CHLORPHENIRAMINE MALEATE,**

Antihistamine

**DEXTROMETHORPHAN HBr**

Cough Suppressant

**Relieves:**

- **Fever & Sore Throat**
- **Sneezing & Runny Nose**
- **Cough**

**Dosing cup included**

**Grape Flavor**

**Ages 6-11**

**4 FL OZ (120 mL)**

**IMPORTANT: Keep this carton for future reference on full labeling.**

**Package contains One Bottle**

**Distributed by:**

**CVS Pharmacy, Inc.**

**One CVS Drive, Woonsocket, RI 02895**

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**CVS.com® 1-800-SHOP CVS**

**V-12431**

**CVS® Quality**

**Money Back Guarantee**

\*This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., distributor of Children's Tylenol® Cold + Cough + Runny Nose.

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**Drug Facts**

**Active ingredients (in each 5 mL)** **Purposes**  
 Acetaminophen 160 mg.....Pain reliever/fever reducer  
 Chlorpheniramine maleate 1 mg.....Antihistamine  
 Dextromethorphan HBr 5 mg.....Cough suppressant

**Uses** ■ temporarily relieves the following cold/flu symptoms:  
 ■ minor aches and pains ■ headache ■ sore throat  
 ■ sneezing and runny nose ■ cough  
 ■ temporarily reduces fever

**Warnings**  
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 ■ blisters ■ rash  
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**Ask a doctor before use if your child has**  
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**Ask a doctor or pharmacist before use if your child is**  
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**When using this product**  
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**Drug Facts (continued)**

■ marked drowsiness may occur  
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**Stop use and ask a doctor if**  
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**Other information**  
 ■ each 5 mL contains: sodium 3 mg  
 ■ store at room temperature

**Inactive ingredients** citric acid, carboxymethylcellulose sodium, D&C Red No. 33, edetate disodium, FD&C Blue No. 1, FD&C Red No. 40, flavor, glycerin, microcrystalline cellulose, propyl gallate, propylene glycol, purified water, sodium benzoate, sorbitol, sucrose, xanthan gum.

**Questions or comments?** 1-866-457-2748



Suspension Liquid

**Children's Cough & Runny Nose**



Compare to the active ingredients in Children's Tylenol® Cold + Cough + Runny Nose™  
 Suspension Liquid

**Children's Cough & Runny Nose**

**ACETAMINOPHEN**  
 Pain reliever; Fever reducer  
**CHLORPHENIRAMINE MALEATE**  
 Antihistamine  
**DEXTROMETHORPHAN HBr**  
 Cough suppressant

- Relieves:**
- Fever & Sore throat
  - Sneezing & Runny nose
  - Cough



**Grape Flavor**  
**Ages 6 to 11**  
**4 FL OZ (120 mL)**

**IMPORTANT:**  
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Package Contains One Bottle

Actual Size

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 One CVS Drive, Woonsocket, RI 02895  
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 V-12431



#688441



Lot:

Exp:

**CVS CHILDRENS COLD PLUS COUGH PLUS RUNNY NOSE**  
 acetaminophen, chlorpheniramine maleate, and dextromethorphan hydrobromide suspension

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-792
Route of Administration	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>Acetaminophen</b> (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)	Acetaminophen	160 mg in 5 mL
<b>Chlorpheniramine Maleate</b> (UNII: V1Q0O9OJ9Z) (Chlorpheniramine - UNII:3U6IO1965U)	Chlorpheniramine Maleate	1 mg in 5 mL
<b>Dextromethorphan Hydrobromide</b> (UNII: 9D2RTI9KYH) (Dextromethorphan - UNII:7355X3ROTS)	Dextromethorphan Hydrobromide	5 mg in 5 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>anhydrous citric acid</b> (UNII: XF417D3PSL)	
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED</b> (UNII: K679OBS311)	
<b>D&amp;C red no. 33</b> (UNII: 9DBA0SBB0L)	
<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>microcrystalline cellulose</b> (UNII: OP1R32D61U)	
<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>sucrose</b> (UNII: C151H8M554)	
<b>xanthan gum</b> (UNII: TTV12P4NEE)	

**Product Characteristics**

<b>Color</b>	PURPLE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	GRAPE	<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-792-04	1 in 1 CARTON	03/30/2020	
1		120 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/30/2020	

