

**CVS CHILDRENS COLD PLUS COUGH PLUS SORE THROAT- acetaminophen and dextromethorphan hydrobromide suspension**  
**CVS PHARMACY**

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**Children's Cold + Cough + Sore Throat Relief**

**Drug Facts**

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

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Acetaminophen 160 mg	Pain reliever/fever reducer
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
  - 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.
- 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
- 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**

**When using this product**

- **do not exceed recommended dose (see overdose warning)**

**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 at 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 the 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	5 mL

48-95	6 to 11 years	10 mL
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**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

### **Inactive ingredients**

carboxymethylcellulose sodium, anhydrous citric acid, D&C red no. 33, disodium edetate, FD&C red no. 40, flavors, glycerin, microcrystalline cellulose, purified water, sodium benzoate, sodium citrate dihydrate, sorbitol solution, sucralose, xanthan gum

### **Questions or comments?**

**1-866-467-2748**

### **PRINCIPAL DISPLAY PANEL**

Compare to the active ingredients in Children's Tylenol® Cold + Cough + Sore Throat\*  
NDC 51316-650-04

#### ***Children's***

#### ***Cold + Cough***

#### ***+ Sore Throat Relief***

**Acetaminophen**, Pain Reliever-Fever Reducer  
Dextromethorphan HBr, Cough Suppressant

*Oral Suspension*

#### ***Ages 4-11 Years***

- **Fever**
- **Sore Throat**
- **Cough**

Ibuprofen free, aspirin free,

No added alcohol

#### ***Bubblegum Flavor***

#### ***Naturally and Artificially Flavored***

4 FL OZ (120 mL)

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

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



**CVS CHILDRENS COLD PLUS COUGH PLUS SORE THROAT**

acetaminophen and dextromethorphan hydrobromide suspension

**Product Information**

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:51316-650

Route of Administration ORAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	160 mg in 5 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 5 mL

### Inactive Ingredients

Ingredient Name	Strength
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

### Product Characteristics

Color	pink	Score	
Shape		Size	
Flavor	BUBBLE GUM	Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-650-04	1 in 1 CARTON	02/01/2023	
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 Drug	M012	02/01/2023	

