

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.

Children's TYLENOL® COLD + COUGH + RUNNY NOSE

Drug Facts

<i>Active ingredients (in each 5 mL)</i>	<i>Purposes</i>
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

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

Weight (lb)	Age (yr)	Dose (mL)
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

**Children's Cold + Cough +
Runny Nose Relief**

Acetaminophen,

Pain Reliever-Fever Reducer

Chlorpheniramine Maleate,

Antihistamine

Dextromethorphan HBr

Cough Suppressant

Oral Suspension

Ages 6-11 Years

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

Grape Flavor

Naturally and Artificially Flavored

4 FL OZ (120 mL)

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

Distributed by:

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

Children's Cold + Cough+ Runny Nose Relief

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

NDC 69842-792-04

Children's Cold + Cough+ Runny Nose Relief

Acetaminophen,
Pain Reliever-Fever Reducer
Chlorpheniramine Maleate,
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Dextromethorphan HBr,
Cough Suppressant

Oral Suspension

Ages 6-11 Years

• Fever • Sore Throat • Sneezing
• Runny Nose • Cough

Grape Flavor

Naturally and Artificially Flavored

4 FL OZ (120 mL)

792GRD400KFC



Lot:

Exp:

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Dextromethorphan HBr 5 mg.....Cough suppressant

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• to make a child sleepy
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Drug Facts (continued)

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• new symptoms occur
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Other information

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

Inactive ingredients: citric acid, carbonylmethylcellulose-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? 1-800-467-2748

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
Acetaminophen (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)	Acetaminophen	160 mg in 5 mL
Chlorpheniramine Maleate (UNII: V1Q0O9OJ9Z) (Chlorpheniramine - UNII:3U6IO1965U)	Chlorpheniramine Maleate	1 mg in 5 mL
Dextromethorphan Hydrobromide (UNII: 9D2RTI9KYH) (Dextromethorphan - UNII:7355X3ROTS)	Dextromethorphan Hydrobromide	5 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
anhydrous citric acid (UNII: XF417D3PSL)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
D&C red no. 33 (UNII: 9DBA0SBB0L)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C blue no. 1 (UNII: H3R47K3TBD)	
FD&C red no. 40 (UNII: WZB9127XOA)	
glycerin (UNII: PDC6A3C0OX)	
microcrystalline cellulose (UNII: OP1R32D61U)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
water (UNII: 059QF0KO0R)	
sodium benzoate (UNII: OJ245FE5EU)	
sorbitol (UNII: 506T60A25R)	
sucrose (UNII: C151H8M554)	
xanthan gum (UNII: TTV12P4NEE)	

Product Characteristics

Color	PURPLE	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

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	

