

**CHILDRENS TYLENOL COLD PLUS FLU- acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide, and phenylephrine hydrochloride suspension**  
**Johnson & Johnson Consumer Inc.**

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**Children's TYLENOL**

**COLD + FLU**

***Drug Facts***

<b><i>Active ingredients (in each 5 mL)</i></b>	<b><i>Purpose</i></b>
Acetaminophen 160 mg	Pain reliever/fever reducer
Chlorpheniramine maleate 1 mg	Antihistamine
Dextromethorphan HBr 5 mg	Cough suppressant
Phenylephrine HCl 2.5 mg	Nasal decongestant

**Uses**

- temporarily relieves the following cold/flu symptoms:
  - minor aches and pains
  - headache
  - sore throat
  - cough
  - stuffy nose
  - sneezing and runny nose
- 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 is allergic to any of the ingredients in this product

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

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- persistent or chronic cough such as occurs with asthma
- cough that occurs with too much phlegm (mucus)
- a breathing problem such as chronic bronchitis
- glaucoma

### **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)**
- 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 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

\* or as directed by a doctor

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

### Other information

- store between 20-25°C (68-77°F)
- **do not use if carton is opened or if carton tape or bottle wrap imprinted "TYLENOL" is broken or missing**

### Inactive ingredients

anhydrous citric acid, D&C red no. 33, FD&C red no. 40, flavors, glycerin, microcrystalline cellulose and carboxymethylcellulose sodium, purified water, sodium benzoate, sorbitol solution, sucrose, xanthan gum

### Questions or comments?

call **1-800-458-1635** (toll-free) or **215-273-8755** (collect)

### PRINCIPAL DISPLAY PANEL

NDC 50580-456-01

**Children's**

**TYLENOL** ®

**COLD +  
FLU**

**Acetaminophen**, Pain Reliever-Fever Reducer  
Chlorpheniramine Maleate, Antihistamine  
Dextromethorphan HBr, Cough Suppressant  
Phenylephrine HCl, Nasal Decongestant

*Oral Suspension*

**Ages 6-11 Years**

- **FEVER**
- **SORE THROAT**
- **SNEEZING**
- **RUNNY NOSE**
- **COUGH**
- **STUFFY NOSE**

4 fl oz (120 mL)

**Bubblegum**  
*Flavor*



SNAP THIS  
CODE OR  
TEXT TYKID  
TO 87715

MSG & DATA RATES  
MAY APPLY  
TEXT HELP FOR HELP.  
TEXT STOP FOR STOP.



How can we help?  
☎ 1-800-458-1635

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- ✓ FEVER
- ✓ SORE THROAT
- ✓ SNEEZING
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- ✓ COUGH
- ✓ STUFFY NOSE



# Children's **TYLENOL**<sup>®</sup> **COLD + FLU**

*Ages 6-11 Years*

• Ibuprofen Free • Alcohol Free • Aspirin Free

## DIRECTIONS:

### STEP 1.

Shake well  
before using



### STEP 2.

Remove child  
protective  
cap

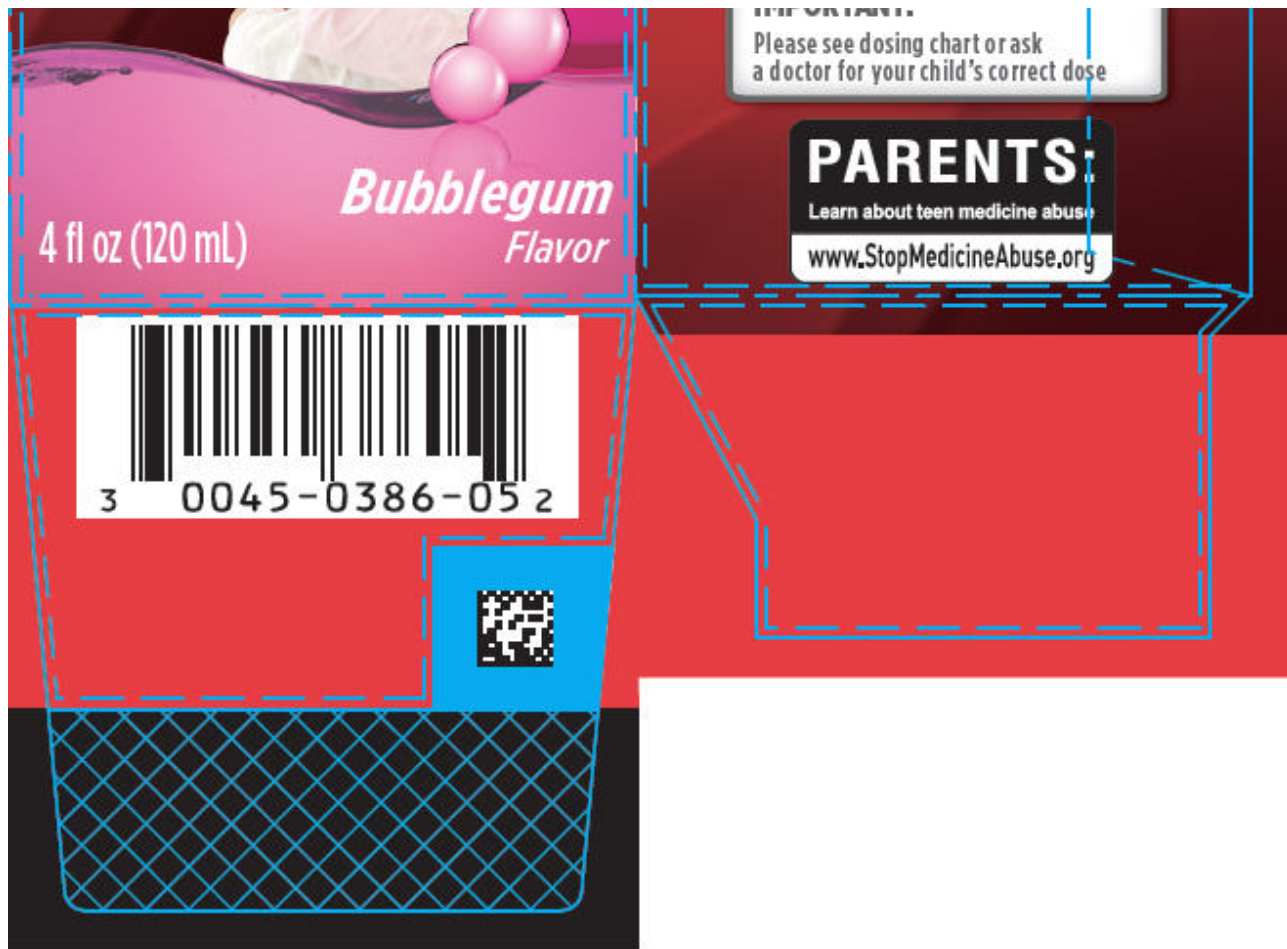


### STEP 3.

Squeeze your  
child's dose  
into the  
dosing cup



IMPORTANT:



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**Drug Facts (continued)**

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Distributed by: **JOHNSON & JOHNSON CONSUMER INC.**

McNeil Consumer Healthcare Division

30037517

Fort Washington, PA 19034 USA

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# CHILDRENS TYLENOL COLD PLUS FLU

acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide, and phenylephrine hydrochloride suspension

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50580-456
<b>Route of Administration</b>	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
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 5 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>D&amp;C RED NO. 33</b> (UNII: 9DBA0SBB0L)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM</b> (UNII: K679OBS311)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SORBITOL SOLUTION</b> (UNII: 8KW3E207O2)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

## Product Characteristics

<b>Color</b>	pink	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	BUBBLE GUM	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-456-01	1 in 1 CARTON	06/26/2017	
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	06/26/2017	

**Labeler** - Johnson & Johnson Consumer Inc. (878046358)

Revised: 1/2024

Johnson & Johnson Consumer Inc.