

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

*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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**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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Chlorpheniramine Maleate, Antihistamine  
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- ✓ SORE THROAT
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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

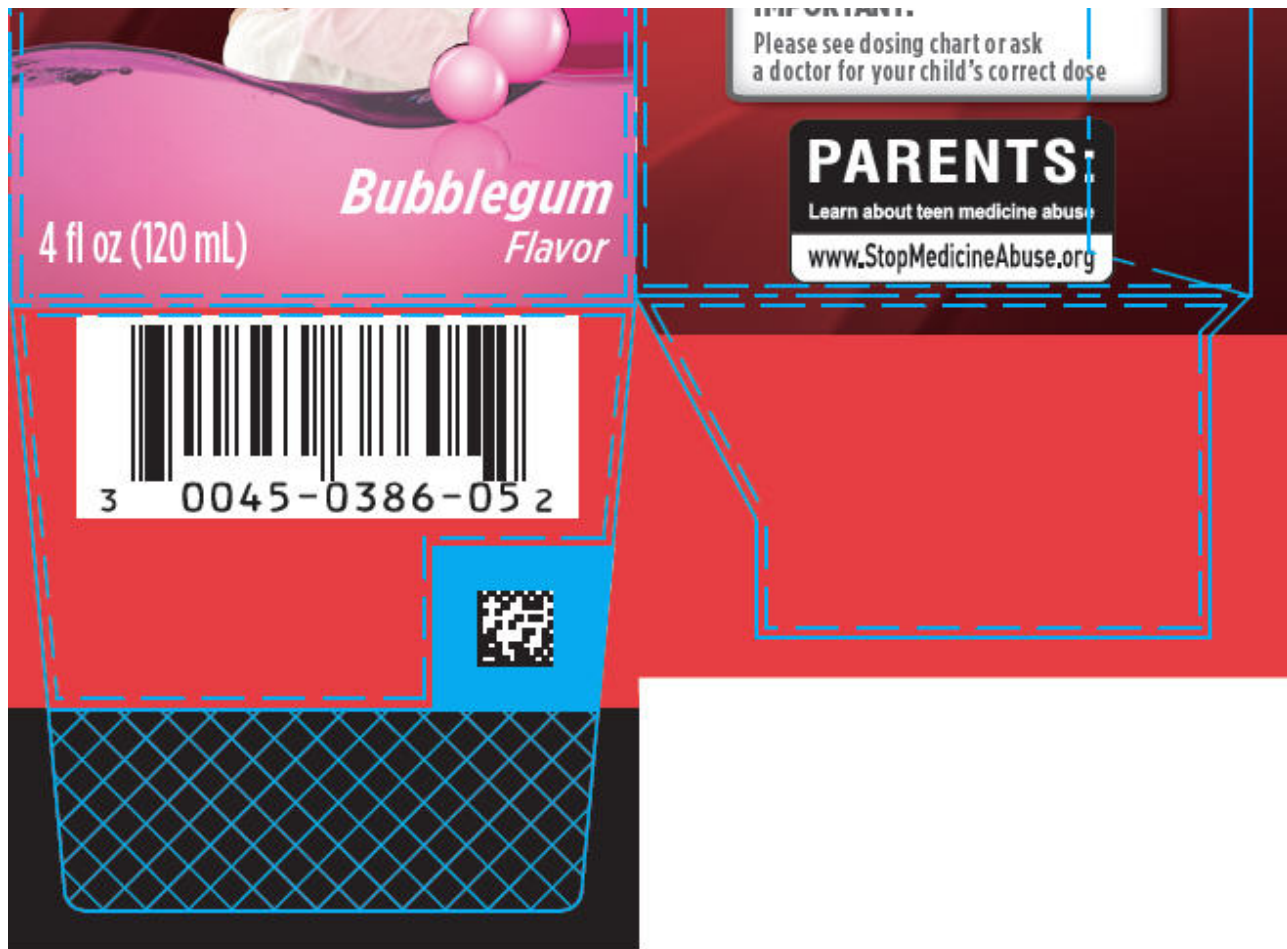


### STEP 3.

Squeeze your  
child's dose  
into the  
dosing cup



IMPORTANT:



**IMPORTANT:**  
Please see dosing chart or ask a doctor for your child's correct dose

**PARENTS:**  
Learn about teen medicine abuse  
[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)



**Drug Facts**

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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: 059QF0K00R)	
<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		
<b>Marketing Information</b>			
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC MONOGRAPH FINAL	part341	06/26/2017	

**Labeler** - Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division (878046358)

Revised: 8/2020

Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division