

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.

**Children's TYLENOL
COLD + FLU**

Drug Facts

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

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

* 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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- ✓ COUGH
- ✓ STUFFY NOSE



Children's **TYLENOL**[®] **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

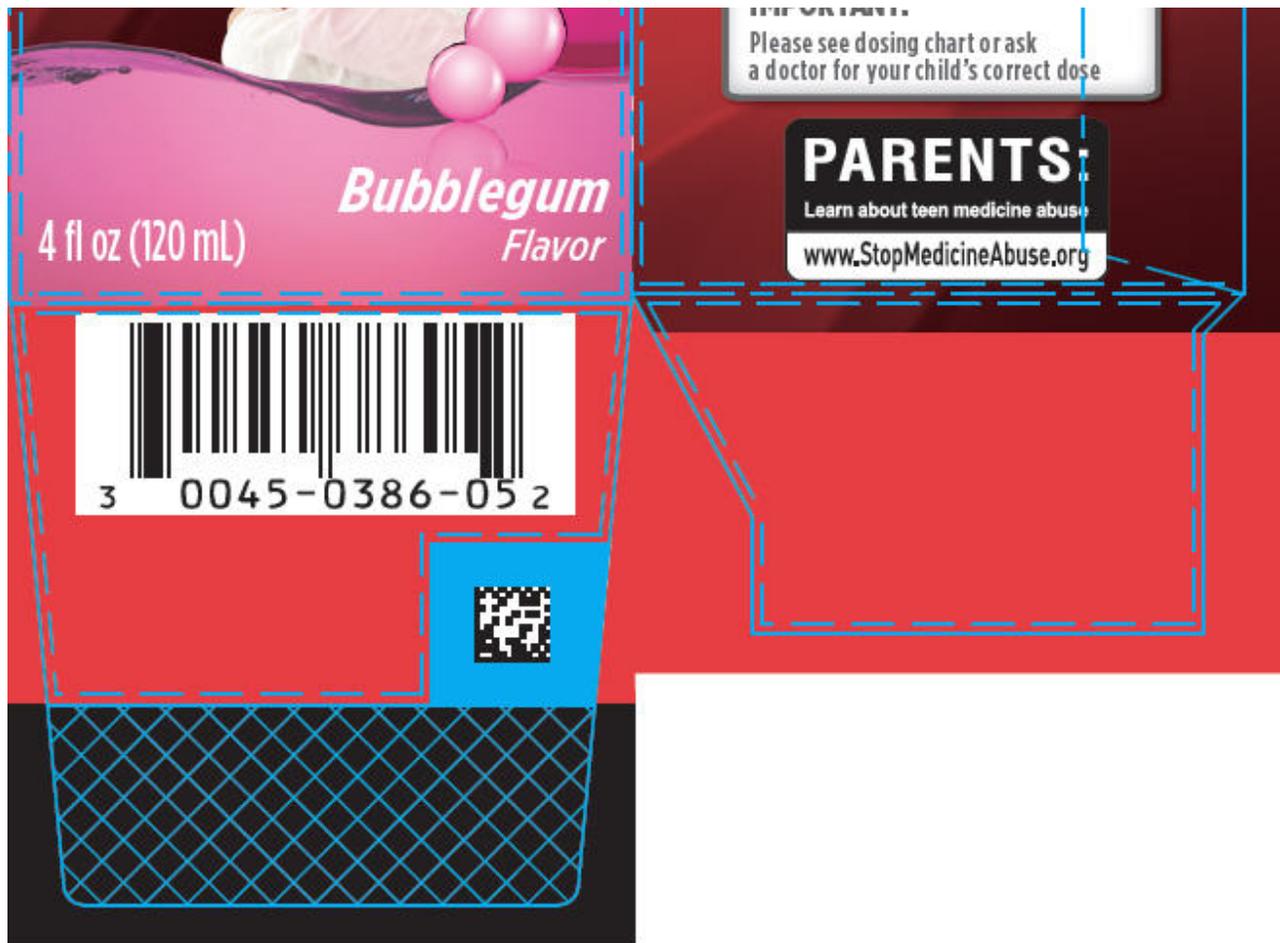


STEP 3.

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

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Fort Washington, PA 19034 USA

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Care To Recycle™

CHILDRENS TYLENOL COLD PLUS FLU

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50580-456
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
Phenylephrine Hydrochloride (UNII: 04JA59TNSJ) (Phenylephrine - UNII:1WS297W6MV)	Phenylephrine Hydrochloride	2.5 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
anhydrous citric acid (UNII: XF417D3PSL)	
D&C red no. 33 (UNII: 9DBA0SBB0L)	
FD&C red no. 40 (UNII: WZB9127XOA)	
glycerin (UNII: PDC6A3C0OX)	
microcrystalline cellulose (UNII: OP1R32D61U)	
carboxymethylcellulose sodium, unspecified form (UNII: K679OBS311)	
water (UNII: 059QF0K00R)	
sodium benzoate (UNII: OJ245FE5EU)	
sorbitol (UNII: 506T60A25R)	
sucrose (UNII: C151H8M554)	
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: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 FINAL	part341	06/26/2017	

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

Revised: 4/2017

Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division