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

Children's TYLENOL

Drug Facts

Active ingredients (in each 5 mL)	Purpose	
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 blue no. 1, 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 50580-299-01

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

Grape

Flavor

4 fl oz (120 mL)





How can we help? *(**1-800-458-1635

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COLD+ FLU

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

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COUGH
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Children's **TYLENOL COLD + FLU** Ages 6-11 Years

buprofen Free • Alcohol Free • Aspirin Free

DIRECTIONS:

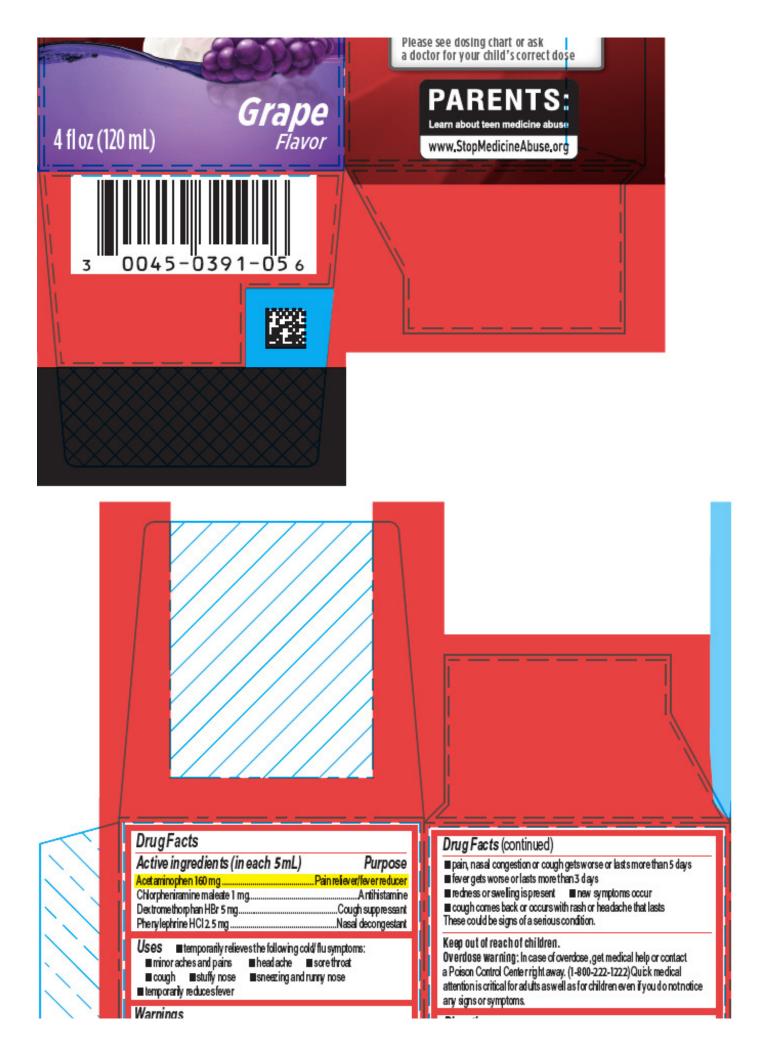
STEP 1. Shake well before using



STEP 2. Remove child protective cap

STEP 3. Squeeze your child's dose into the dosing cup

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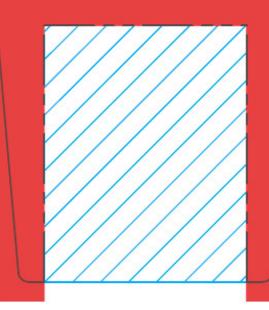
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Distributed by: JOHNSON & JOHNSON CONSUMER INC. McNeil Consumer Healthcare Division 30037519 Fort Washington, PA 19034 USA @J&JCI 2016 www.tylenol.com



CHILDRENS TYLENOL COLD PLUS FLU

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Product Info	rmation						
Product Type		HUMAN OTC DRUG	Item Code (Source) NDC:50580		0-299		
Route of Admir	nistration	ORAL					
-							
Active Ingred	lient/Active	Moiety					
	Ingree	lient Name			Basis of Str	ength	Strengt
ACETAMINOPHEN	(UNII: 36209ITL	9D) (ACETAMINOPHEN -	UNII:36209IT	L9D) AC	ETAMINOPHEN		160 mg in 5 mL
CHLORPHENIRAM UNII:3U6IO1965U)	IINE MALEATE (UNII: V1Q0O9OJ9Z) (CH	LORPHENIRAM		CHLORPHENIRAMINE MALEATE		1 mg in 5 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)			DEXTROMETHORPHAN HYDROBROMIDE		5 mg in 5 mL		
PHENYLEPHRINE UNII:1WS297W6MV		DE (UNII: 04JA59TNSJ) (I	PHENYLEPHRIN		IENYLEPHRINE DROCHLORIDE		2.5 mg in 5 mL
Inactive Ingr	edients						
		Ingredient Na	me			9	Strength
ANHYDROUS CIT	RIC ACID (UNII:)	(F417D3PSL)					
D&C RED NO. 33							
FD&C BLUE NO.							
FD&C RED NO. 4	0 (UNII: WZ B912	7XOA)					
GLYCERIN (UNII: F	DC6A3C0OX)						
MICROCRYSTALL	INE CELLULOSI	(UNII: OP1R32D61U)					
		DDIUM, UNSPECIFIED	FORM (UNII:	K679OB9	5311)		
WATER (UNII: 059	QF0KO0R)						
SODIUM BENZOA	TE (UNII: OJ245F	E5EU)					
SORBITOL SOLU	FION (UNII: 8KW3	E207O2)					
SUCROSE (UNII: C	151H8M554)						
XANTHAN GUM (L	JNII: TTV12P4NEE	E)					
Product Char	acteristics						
Color		purple	Score				
Shape							
Flavor		GRAPE Imprint Code					
ontains							
Packaging							
Packaging # Item Code	Pa	ckage Descriptior	1		eting Start Date		ting End ate

	.20 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 Dru	g M012	06/26/2017		

Labeler - Johnson & Johnson Consumer Inc. (878046358)

Revised: 1/2024

Johnson & Johnson Consumer Inc.