

**TYLENOL COLD PLUS FLU SEVERE- acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride solution**  
Kenvue Brands LLC

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**TYLENOL<sup>®</sup> Cold + Flu Severe**

***Drug Facts***

<b><i>Active ingredients (in each 30 mL)</i></b>	<b><i>Purpose</i></b>
Acetaminophen 650 mg	Pain reliever/fever reducer
Dextromethorphan HBr 20 mg	Cough suppressant
Guaifenesin 400 mg	Expectorant
Phenylephrine HCl 10 mg	Nasal decongestant

**Uses**

- temporarily relieves the following cold/flu symptoms:
  - minor aches and pains
  - headache
  - sore throat
  - nasal congestion
  - cough
- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive
- temporarily reduces fever

**Warnings**

**Liver warning**

- This product contains acetaminophen. Severe liver damage may occur if you take
- more than 4,000 mg of acetaminophen in 24 hours
  - with other drugs containing acetaminophen
  - 3 or more alcoholic drinks every day while using this product

**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.
- if you are now 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 prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- if you have ever had an allergic reaction to this product or any of its ingredients

## **Ask a doctor before use if you have**

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough that occurs with too much phlegm (mucus)

**Ask a doctor or pharmacist before use if you are** taking the blood thinning drug warfarin

## **When using this product do not exceed recommended dose**

### **Stop use and ask a doctor if**

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion or cough gets worse or lasts more than 7 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.

**If pregnant or breast-feeding**, ask a health professional before use.

**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

- **do not take more than directed (see overdose warning)**
- mL = milliliter
- use only enclosed dosing cup designed for use with this product. Do not use any other dosing device.

adults and children 12 years and over	<ul style="list-style-type: none"><li>▪ take 30 mL in the dosing cup provided every 4 hours while symptoms last</li><li>▪ do not take more than 150 mL in 24 hours, unless directed by a doctor</li></ul>
children under 12 years	ask a doctor

## Other information

- each 30 mL contains: **sodium 10 mg**
- store between 20-25°C (68-77°F).
- **do not use if neck band imprinted with "WARMING SENSATION" or foil inner seal imprinted with "TYLENOL" is broken or missing**

## Inactive ingredients

anhydrous citric acid, FD&C blue no. 1, FD&C red no. 40, FD&C yellow no. 6, flavors, glycerin, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucralose

## Questions or comments?

call **1-877-895-3665** (toll-free) or **215-273-8755** (collect)

## PRINCIPAL DISPLAY PANEL

NDC 50580-403-08  
30049843

Warming Honey Lemon Flavor

TYLENOL®  
FOR  
ADULTS

COLD + FLU SEVERE

Acetaminophen,  
Dextromethorphan HBr, Phenylephrine HCl, Guaifenesin  
Pain Reliever-Fever Reducer, Cough Suppressant,  
Nasal Decongestant, Expectorant

Alcohol Free

DAY

NON-DROWSY

- HEAD + BODY ACHES
- FEVER + SORE THROAT
- COUGH
- NASAL CONGESTION
- MUCUS + CHEST CONGESTION

8 fl oz (240 mL)

NDC 50580-403-08 30049843

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# TYLENOL<sup>®</sup>

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OPEN TO READ DRUG FACTS  
(Warnings, Directions...)

PEEL

EXP./LOT:

30049843

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**DO NOT USE WITH OTHER MEDICINES  
CONTAINING ACETAMINOPHEN**



3 0045-0525-086

### Drug Facts

Active ingredients Purpose

### Drug Facts (continued)

■ temporarily reduces fever

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**(in each 30 mL)**

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**Drug Facts (continued)**

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**PARENTS:**

Learn about teen medicine abuse

[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)

**TYLENOL®**  
COLD + FLU SEVERE

How can we help?  
**1-877-895-3665**

Acetaminophen (650 mg per 30 mL)  
Dextromethorphan HBr (20 mg per 30 mL)  
Guaifenesin (400 mg per 30 mL)  
Phenylephrine HCl (10 mg per 30 mL)

8 fl oz (240 mL)

Distributed by:  
**JOHNSON & JOHNSON CONSUMER INC.**  
McNeil Consumer Healthcare Division  
Fort Washington, PA 19034 USA  
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30049845

# TYLENOL COLD PLUS FLU SEVERE

acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride solution

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50580-403
<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	650 mg in 30 mL
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 30 mL
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 30 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 30 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SORBITOL SOLUTION</b> (UNII: 8KW3E207O2)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	

## Product Characteristics

<b>Color</b>	brown, yellow (Amber colored)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	HONEY, LEMON	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-403-08	240 mL in 1 BOTTLE, PLASTIC; Type 1: Convenience Kit of Co-Package	07/05/2010	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	07/05/2010	

**Labeler** - Kenvue Brands LLC (118772437)

Revised: 11/2024

Kenvue Brands LLC