

**TYLENOL COLD PLUS MUCUS SEVERE- acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride solution**  
**Johnson & Johnson Consumer Inc.**

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**TYLENOL Cold + Mucus Severe**

**Drug Facts**

<b>Active ingredients (in each 15 mL)</b>	<b>Purpose</b>
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

**Uses**

- for the temporary relief of 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 15 mL contains:** sodium 5 mg
- store between 20-25°C (68-77°F). Do not refrigerate.
- **do not use if neck band imprinted with "TYLENOL COLD + MUCUS SEVERE" or foil inner seal imprinted with "SAFETY SEAL®" is broken or missing**

### Inactive ingredients

alcohol, anhydrous citric acid, FD&C blue no. 1, flavor, 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 50580-511-01

**TYLENOL®**  
FOR ADULTS

### **COLD + MUCUS SEVERE**

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

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

**DAY**  
NON-DROWSY

**COOL**  
**BURST**®

Alcohol 0.7%

**8 fl oz (240 mL)**

30040605

NDC 50580-511-01

# TYLENOL<sup>®</sup>

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**COLD + MUCUS SEVERE**

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



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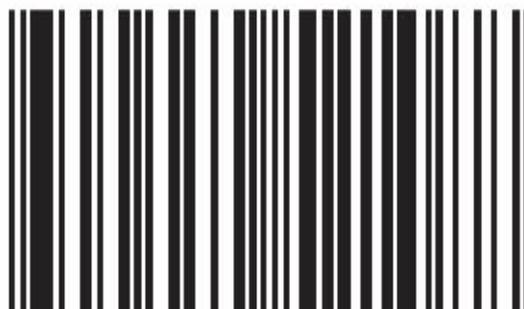
OPEN TO READ DRUG FACTS →  
(Warnings, Directions...)

PEEL



30042165 Do not use if neck band imprinted with  
“TYLENOL COLD + MUCUS SEVERE” or  
foil inner seal imprinted with “SAFETY  
SEAL<sup>®</sup>” is broken or missing.

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



3 0045-0521-088

# TYLENOL®

COLD + MUCUS SEVERE

## Drug Facts

### Active ingredients (in each 15 mL) Purpose

Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Guaifenesin 200 mg	Expectorant
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## Uses

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  - minor aches and pains
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  - nasal congestion
  - helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive
  - sore throat
  - cough

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

SNAP THIS CODE OR TEXT TYCOLD8 TO 87715

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



Acetaminophen (325 mg per 15 mL)  
Dextromethorphan HBr (10 mg per 15 mL)  
Phenylephrine HCl (5 mg per 15 mL)  
Guaifenesin (200 mg per 15 mL)

8 fl oz (240 mL)

Made in Canada

Distributed by:

JOHNSON & JOHNSON CONSUMER INC.  
McNeil Consumer Healthcare Division  
Fort Washington, PA 19034 USA

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30042165

## Drug Facts (continued)

- temporarily reduces fever

## Warnings

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- 3 or more alcoholic drinks every day while using this product

**Allergy alert:** acetaminophen may

## Drug Facts (continued)

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

cause severe skin reactions.

Symptoms may include:

- skin reddening
- blisters
- rash

acetaminophen, ask a doctor or pharmacist.

- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for

### **Drug Facts** (continued)

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.

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

- liver disease
- heart disease
- high blood pressure
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- diabetes

### **Drug Facts** (continued)

- 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

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**Stop use and ask a doctor if**

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion or cough

### **Drug Facts** (continued)

gets worse or lasts more than 7 days

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	directed by a doctor
children under 12 years	ask a doctor

### Drug Facts (continued)

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Do not refrigerate.
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### Drug Facts (continued)

#### Questions or comments?

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**PARENTS:**

Learn about teen medicine abuse

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

## TYLENOL COLD PLUS MUCUS SEVERE

acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50580-511
<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	325 mg in 15 mL
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 15 mL

<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 15 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 15 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<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>	blue	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	BERRY, MINT	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-511-01	240 mL in 1 BOTTLE, PLASTIC; Type 1: Convenience Kit of Co-Package	06/22/2015	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	06/22/2015	

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

Revised: 1/2024

Johnson & Johnson Consumer Inc.