

**EXTRA STRENGTH TYLENOL SEVERE COUGH PLUS SORE THROAT NIGHT-  
acetaminophen, dextromethorphan hydrobromide and doxylamine  
succinate. liquid  
Johnson & Johnson Consumer Inc.**

**Extra Strength TYLENOL® Severe Cough + Sore Throat Night**

***Drug Facts***

<b><i>Active ingredients (in each 30 mL)</i></b>	<b><i>Purpose</i></b>
Acetaminophen 1,000 mg	Pain reliever/fever reducer
Dextromethorphan HBr 30 mg	Cough suppressant
Doxylamine Succinate 12.5 mg	Antihistamine

**Uses**

temporarily relieves these common cold/flu symptoms:

- minor aches and pains
- headache
- sore throat
- cough
- sneezing and runny nose

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
- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma 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
- taking sedatives or tranquilizers

**When using this product**

- **do not exceed recommended dose**
- excitability may occur, especially in children
- marked drowsiness may occur
- alcohol, sedatives and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery

**Stop use and ask a doctor if**

- pain 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)**
- **shake well before using**
- 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 6 hours while symptoms last</li><li>▪ do not take more than 90 mL in 24 hours, unless directed by a doctor</li><li>▪ do not use for more than 10 days unless directed by a doctor</li></ul>
children under 12 years	ask a doctor

## Other information

- each 30 mL contains: **sodium 19 mg**
- store between 20-25°C (68-77°F)
- **do not use if neck band imprinted with "INSTANT COOLING SENSATION" or foil inner seal imprinted with "TYLENOL" is broken or missing**

## Inactive ingredients

anhydrous citric acid, carboxymethylcellulose sodium, FD&C blue no. 1, FD&C red no. 40, flavors, glycerin, microcrystalline cellulose and carboxymethylcellulose sodium, poloxamer, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose

## Questions or comments?

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

## PRINCIPAL DISPLAY PANEL

**NDC 50580-243-01**

**EXTRA STRENGTH TYLENOL®**

FOR ADULTS

**SEVERE COUGH + SORE THROAT**

**NEW!**

**DOSAGE + DIRECTIONS**

**Acetaminophen,**

Dextromethorphan HBr, Doxylamine Succinate  
Pain Reliever-Fever Reducer, Cough Suppressant, Antihistamine

- **HEAD + BODY ACHES**
- **FEVER + SORE THROAT**
- **COUGH**

## FROSTED BERRY

**8 fl oz (240 mL)**

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

**PEEL**



30050189

Do not use if neck band imprinted with  
"INSTANT COOLING SENSATION" or  
foil inner seal imprinted with  
"TYLENOL" is broken or missing

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



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## Drug Facts

### Active ingredients Purpose (in each 30 mL)

Acetaminophen 1,000 mg ..... Pain reliever/  
fever reducer

Dextromethorphan HBr 30 mg ..... Cough  
suppressant

Doxylamine succinate 12.5 mg ..... Antihistamine

### Uses

- temporarily relieves these common cold/flu symptoms:
  - minor aches and pains
  - headache
  - sore throat
  - cough
  - sneezing and runny nose
- temporarily reduces fever

## Drug Facts (continued)

### 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.



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

**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 ▶

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

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
- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma or emphysema ▶

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

- cough that occurs with too much phlegm (mucus)

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- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

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- be careful when driving a motor vehicle or operating machinery ▶

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

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

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These could be signs of a serious condition.

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## Drug Facts (continued)

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)**

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■ 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

■ take 30 mL in the dosing cup provided every 6 hours while symptoms last

■ do not take more than 90 mL in 24 hours, unless directed by a doctor

## Drug Facts (continued)

■ do not use for more than 10 days unless directed by a doctor

children  
under  
12 years

ask a doctor

### Other information

■ each 30 mL contains: **sodium 19 mg**

■ store between 20-25°C (68-77°F)

■ **do not use if neck band imprinted with “INSTANT COOLING SENSATION” or foil inner seal imprinted with “TYLENOL” is broken or missing**

## Drug Facts (continued)

### Inactive ingredients

anhydrous citric acid, carboxymethylcellulose sodium, FD&C blue no. 1, FD&C red no. 40, flavors, glycerin, microcrystalline cellulose and carboxymethylcellulose sodium, poloxamer, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose

### Questions or comments?

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

# PARENTS:

Learn about teen medicine abuse

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

**Extra Strength**  
**TYLENOL** FOR ADULTS  
**SEVERE COUGH**  
**+ SORE THROAT**  
**Night**

*How can we help?*

**1-877-895-3665**

Acetaminophen  
(1,000 mg per 30 mL)

Dextromethorphan HBr  
(30 mg per 30 mL)

Doxylamine succinate  
(12.5 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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**30050189**

# EXTRA STRENGTH TYLENOL SEVERE COUGH PLUS SORE THROAT NIGHT

acetaminophen, dextromethorphan hydrobromide and doxylamine succinate. liquid

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50580-243
Route of Administration	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	1000 mg in 30 mL
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 30 mL
<b>DOXYLAMINE SUCCINATE</b> (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM</b> (UNII: K679OBS311)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<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>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	

## Product Characteristics

Color	purple	Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:50580-243-01	240 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/19/2023	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012		06/19/2023	

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

Revised: 1/2024

Johnson & Johnson Consumer Inc.