

**EXTRA STRENGTH TYLENOL SEVERE COUGH PLUS SORE THROAT NIGHT-
acetaminophen, dextromethorphan hydrobromide and doxylamine
succinate. liquid
Kenvue Brands LLC**

Extra Strength TYLENOL® Severe Cough + Sore Throat Night

Drug Facts

<i>Active ingredients (in each 30 mL)</i>	<i>Purpose</i>
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">▪ 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▪ 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**

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**

NIGHT

FROSTED BERRY

8 fl oz (240 mL)

NDC 50580-243-01 30054377 **EXTRA STRENGTH**

TYLENOL[®] FOR ADULTS

SEVERE COUGH

NEW! DOSAGE + DIRECTIONS **+ SORE THROAT**

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

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- HEAD + BODY ACHES
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- COUGH

FROSTED BERRY

8 fl oz (240 mL)

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

189 Do not use if neck band imprinted with "INSTANT COOLING SENSATION" or foil inner seal imprinted with



Drug Facts

Active ingredients (in each 30 mL)	Purpose
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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

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- 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.

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

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 ▶

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
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Drug Facts (continued)

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- excitability may occur, especially in children
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Drug Facts (continued)

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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)
- shake well before using
- mL = milliliter

Drug Facts (continued)

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

children under 12 years	ask a doctor
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Other information

- 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

Other information

- each 30 mL contains: sodium 19 mg
- store between 20-25°C (68-77°F)
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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

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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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	
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)		ACETAMINOPHEN	1000 mg in 30 mL	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)		DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 30 mL	
DOXYLAMINE SUCCINATE (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)		DOXYLAMINE SUCCINATE	12.5 mg in 30 mL	
Inactive Ingredients				
Ingredient Name			Strength	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
GLYCERIN (UNII: PDC6A3C0OX)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
SORBITOL (UNII: 506T60A25R)				
SUCRALOSE (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
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 - Kenvue Brands LLC (118772437)

