EXTRA STRENGTH TYLENOL SEVERE COUGH PLUS SORE THROAT DAYacetaminophen and dextromethorphan hydrobromide liquid Kenvue Brands LLC

Extra Strength TYLENOL® Severe Cough + Sore Throat Day

Drug Facts

Active ingredients (in each 30 mL)

Acetaminophen 1,000 mg

Dextromethorphan HBr 30 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Uses

- temporarily relieves these common cold/flu symptoms:
- minor aches and pains
- headache
- sore throat
- cough
- 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
- 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

When using this product

do not exceed recommended dose

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,

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	 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 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)

PRINICIPAL DISPLAY PANEL

NEW

NDC 50580-140-08

EXTRA STRENGHT TYLENOL ®

FOR ADULTS

SEVERE COUGH + SORE THROAT

Acetaminophen,

Dextromethorphan HBr, Pain Reliever-Fever Reducer, Cough Suppressant

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

DAY

COOLING CHERRY 8 fl oz (240 mL)



PEEL



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Dextromethorphan HBr 30 mg...... Cough suppressant

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 - cough
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Drug Facts (continued)

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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
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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

Drug Facts (continued)

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

- 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.

Drug Facts (continued)

- 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
- persistent or chronic cough such as occurs with smoking, asthma or emphysema
- cough that occurs with too much phlegm (mucus)

Drug Facts (continued)

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

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children under 12 years

ask a doctor

Drug Facts (continued)

Other information

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Inactive ingredients

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

Drug Facts (continued)

Questions or comments? call 1-877-895-3665 (toll-free) or 215-273-8755 (collect)

PARENTS:

Learn about teen medicine abuse

www.StopMedicineAbuse.org



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

Acetaminophen (1,000 mg per 30 mL) Dextromethorphan HBr (30 mg per 30 mL)

8 fl oz (240 mL)

Distributed by: Kenvue Brands LLC Summit, NJ 07901 Kenvue Brands LLC 2025

EXTRA STRENGTH TYLENOL SEVERE COUGH PLUS SORE THROAT DAY

acetaminophen and dextromethorphan hydrobromide liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:50580-140

Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	1000 mg in 30 mL	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 30 mL	

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K6790BS311)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SUCRALOSE (UNII: 96K6UQ3ZD4)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
GLYCERIN (UNII: PDC6A3C0OX)		
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)		
SORBITOL (UNII: 506T60A25R)		

Product Characteristics			
Color	red	Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-140- 08	240 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/06/2025	

Marketing Information			
Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
OTC Monograph Drug	M012	06/06/2025	

Labeler - Kenvue Brands LLC (118772437)

Revised: 3/2025 Kenvue Brands LLC