

**TYLENOL COLD PLUS FLU MULTI-SYMPTOM GELS DAY PLUS NIGHT-  
acetaminophen,dextromethorphan hydrobromide, doxylamine succinate  
Kenvue Brands LLC**

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**TYLENOL® COLD + FLU MULTI-SYMPTOM LIQUID GELS DAY + NIGHT  
TYLENOL® COLD + FLU MULTI-SYMPTOM LIQUID GELS DAY**

***Drug Facts***

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Active ingredient (in each capsule)	Purpose
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant

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**Uses**

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

**Warnings**

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,** 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)**

adults and children 12 years and over	■ take 2 capsules every 4 hours while symptoms last ■ do not take more than 8 capsules in 24 hours
children 4 to under 12 years	ask a doctor
children under 4 years	do not use

## Other information

- store between 20-25°C (68-77°F)
- avoid high humidity and excessive heat above 40°C (104°F)
- protect from light
- **do not use if blister unit is torn or broken**

## Inactive ingredients

FD&C red no. 40, FD&C yellow no. 6, gelatin, glycerin, lecithin, mineral oil, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution

## Questions or comments?

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

## **TYLENOL® COLD + FLU MULTI-SYMPTOM LIQUID GELS NIGHT**

### **Drug Facts**

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#### **Active ingredient (in each capsule)**

Acetaminophen 325 mg

Dextromethorphan HBr 15 mg

Doxylamine succinate 6.25 mg

#### **Purpose**

Pain reliever/fever reducer

Cough suppressant

Antihistamine

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## Uses

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

adults and children 12 years and over	<ul style="list-style-type: none"> <li>■ take 2 capsules every 6 hours while symptoms last</li> <li>■ do not take more than 8 capsules in 24 hours</li> </ul>
children 4 to under 12 years	ask a doctor
children under 4 years	do not use

### **Other information**

- store between 20-25°C (68-77°F)
- avoid high humidity and excessive heat above 40°C (104°F)
- protect from light
- **do not use if blister unit is torn or broken**

### **Inactive ingredients**

D&C yellow no. 10, FD&C blue no. 1, gelatin, glycerin, lecithin, mineral oil, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution

### **Questions or comments?**

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

### **PRINCIPAL DISPLAY PANEL**

NDC 50580-132-24

NEW

TYLENOL®

*FOR ADULTS*

COLD & FL

MULTI SYMPTOM  
LIQUID GELS

**Acetaminophen,**

Dextromethorphan HBr

Pain Reliever-Fever Reducer,  
Cough Suppressant

**DAY**

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

Actual Size

**16 LIQUID GELS**

**Acetaminophen,**

Dextromethorphan HBr, Doxylamine Succinate  
Pain Reliever-Fever Reducer,

Cough Suppressant, Antihistamine

**NIGHT**

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

Actual Size

**8 LIQUID GELS**

**TOTAL 24 LIQUID GELS\***

\*LIQUID FILLED CAPSULES

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



**Drug Facts (continued)**

**Warnings:**

- Do not take more than directed (see overdose warning)
- Do not take more than 7 capsules every 4 hours while symptoms last and over
- Do not take more than 24 capsules in 24 hours
- Do not take Tylenol with alcohol
- Do not take Tylenol with other products containing acetaminophen

**Other information:**

- Keep out of reach of children
- 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)
- adults and children 12 years and over: take 2 capsules every 4 hours while symptoms last and over
- children 4 to under 12 years: ask a doctor
- children under 4 years: do not use

**Drug Facts (continued)**

**Warnings:**

- Do not take more than directed (see overdose warning)
- Do not take more than 7 capsules every 4 hours while symptoms last and over
- Do not take more than 24 capsules in 24 hours
- Do not take Tylenol with alcohol
- Do not take Tylenol with other products containing acetaminophen

**Other information:**

- Keep out of reach of children
- 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)
- adults and children 12 years and over: take 2 capsules every 4 hours while symptoms last and over
- children 4 to under 12 years: ask a doctor
- children under 4 years: do not use

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**TYLENOL** FOR ADULTS  
**COLD + FLU MULTI-SYMP TOM LIQUID GELS**

**DO NOT USE IF BULSTER UNIT IS TORN OR BROKEN**

**NEW**

**TYLENOL** FOR ADULTS  
**COLD & FLU MULTI-SYMP TOM LIQUID GELS**

NDC 50580-132-24

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

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

**DAY**

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

**NIGHT**

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

**16 LIQUID GELS** (Actual Size)

**8 LIQUID GELS** (Actual Size)

**TOTAL 24 LIQUID GELS\*** (LIQUID FILLED CAPSULES)

**PARENTS:** www.StephMed.com/24

**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)
- adults and children 12 years and over: take 2 capsules every 4 hours while symptoms last and over
- children 4 to under 12 years: ask a doctor
- children under 4 years: do not use

**TYLENOL COLD + FLU MULTI-SYMP TOM LIQUID GELS DAY**

**Drug Facts**

**Active ingredient (in each capsule):** Acetaminophen 325 mg, Dextromethorphan HBr 1 mg, Doxylamine Succinate 2 mg

**Other ingredients:** Hydroxypropyl methylcellulose, croscarmellose sodium, polyethylene glycol, polyethylene glycol 400, polyethylene glycol 600, polyethylene glycol 800, polyethylene glycol 1000, polyethylene glycol 1500, polyethylene glycol 2000, polyethylene glycol 3000, polyethylene glycol 4000, polyethylene glycol 6000, polyethylene glycol 8000, polyethylene glycol 10000, polyethylene glycol 15000, polyethylene glycol 20000, polyethylene glycol 30000, polyethylene glycol 40000, polyethylene glycol 60000, polyethylene glycol 80000, polyethylene glycol 100000

**Warnings:**

- Do not take more than directed (see overdose warning)
- Do not take more than 7 capsules every 4 hours while symptoms last and over
- Do not take more than 24 capsules in 24 hours
- Do not take Tylenol with alcohol
- Do not take Tylenol with other products containing acetaminophen

**Directions:**

- do not take more than directed (see overdose warning)
- adults and children 12 years and over: take 2 capsules every 4 hours while symptoms last and over
- children 4 to under 12 years: ask a doctor
- children under 4 years: do not use

**Drug Facts (continued)**

**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, 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)
- adults and children 12 years and over: take 2 capsules every 4 hours while symptoms last and over
- children 4 to under 12 years: ask a doctor
- children under 4 years: do not use

**Drug Facts (continued)**

**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
- 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

**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, 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.

**TYLENOL COLD PLUS FLU MULTI-SYMP TOM GELS DAY PLUS NIGHT**  
acetaminophen, dextromethorphan hydrobromide, doxylamine succinate kit

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50580-132
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-132-24	1 in 1 PACKAGE; Type 0: Not a Combination Product	09/25/2024	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	2 BLISTER PACK	16
Part 2	1 BLISTER PACK	8

### Part 1 of 2

## TYLENOL COLD PLUS FLU MULTI-SYMPATOM LIQUID GELS DAY

acetaminophen, dextromethorphan hydrobromide capsule, liquid filled

### Product Information

<b>Item Code (Source)</b>	NDC:50580-130
<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
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	

### Product Characteristics

<b>Color</b>	orange	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	21mm
<b>Flavor</b>		<b>Imprint Code</b>	TY;DT
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		2 in 1 KIT		
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	09/25/2024	

### Part 2 of 2

## TYLENOL COLD PLUS FLU MULTI-SYMPTOM GELS NIGHT

acetaminophen, dextromethorphan hydrobromide and doxylamine succinate capsule, liquid filled

### Product Information

<b>Item Code (Source)</b>	NDC:50580-131
<b>Route of Administration</b>	ORAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
<b>DOXYLAMINE SUCCINATE</b> (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	

<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	

Product Characteristics			
<b>Color</b>	green	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	21mm
<b>Flavor</b>		<b>Imprint Code</b>	TY;NT
<b>Contains</b>			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 KIT		
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	09/25/2024	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	09/25/2024	

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