

**EXTRA STRENGTH TYLENOL COLD PLUS FLU MULTI-ACTION DAY-  
acetaminophen, pseudoephedrine hydrochloride, and dextromethorphan  
hydrobromide tablet, film coated  
Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Extra Strength TYLENOL Cold + Flu Multi-Action**

**Day**

**Drug Facts**

<b>Active ingredients (in each caplet)</b>	<b>Purpose</b>
Acetaminophen 500 mg	Pain reliever/fever reducer
Dextromethorphan HBr 15 mg	Cough suppressant
Pseudoephedrine HCl 30 mg	Nasal decongestant

**Uses**

- temporarily relieves these common cold/flu symptoms:
  - minor aches and pains
  - headache
  - sore throat
  - nasal congestion
  - cough
  - sinus congestion and pressure
- helps clear nasal passages
- promotes nasal and sinus drainage
- 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 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)**

adults and children 12 years and over	<ul style="list-style-type: none"><li>▪ take 2 caplets every 6 hours while symptoms last</li><li>▪ do not take more than 6 caplets 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

- store between 20 - 25°C (68 - 77°F).
- **do not use if blister unit is torn or broken**

### Inactive ingredients

carnauba wax, hypromellose, magnesium stearate, microcrystalline cellulose, powdered cellulose, pregelatinized starch, propylene glycol, sodium starch glycolate, titanium dioxide

### Questions or comments?

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

### PRINCIPAL DISPLAY PANEL

NEW  
NDC 50580-344-01  
Extra Strength

TYLENOL®  
FOR ADULTS

COLD + FLU MULTI-ACTION

Acetaminophen,  
Dextromethorphan HBr, Pseudoephedrine HCl

Pain Reliever-Fever Reducer, Cough Suppressant, Nasal Decongestant

DAY

NON-DROWSY

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

Actual Size

24 CAPLETS

0045014724 0

**PARENTS:**  
Learn about teen medicine abuse  
[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)

30042004

**Drug Facts (continued)**  
Other information ■ Store between 20°-25°C (68°-77°F). Do not use if water unit is torn or broken.  
**Inactive ingredients** camellid wax, hypromellose, magnesium stearate,  
sodium starch glycolate, titanium dioxide

**Drug Facts (continued)**  
**Directions** ■ Do not take more than directed (see overdose warning).  
Adults and children ■ Take 2 caplets every 6 hours while symptoms last. Do not take more than 6 caplets in 24 hours, unless directed by a doctor.  
Hidden under 12 years ■ Do not use by more than 10 days unless directed by a doctor. Ask a doctor.

**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. ■ More alcohol: do not drink every day while using this product. ■ Skin redness, itching, rash, hives, or blisters. ■ Allergy alert: acetaminophen may cause severe skin reactions. Symptoms may include: hives, rash, blisters, skin redness, itching, and seek medical help right away. ■ Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied by fever, or if you have difficulty swallowing, consult your doctor.  
**Uses** ■ Temporarily relieves these common cold symptoms: ■ minor aches and pains, ■ headache, ■ sore throat, ■ nasal congestion, ■ cough, ■ sinus congestion and pressure. ■ Temporarily reduces fever. ■ Helps clear nasal passages. ■ Relieves nasal and sinus drainage.

**Drug Facts (continued)**  
**Active ingredients (in each caplet)**  
Acetaminophen 500mg, Dextromethorphan HBr 15 mg, Pseudoephedrine HCl 30 mg.  
**Purpose** ■ Pain reliever/fever reducer. ■ Cough suppressant. ■ Nasal decongestant.  
**Ask a doctor before use if you have** ■ liver disease ■ high blood pressure ■ thyroid disease ■ heart disease ■ trouble swallowing or enlarged prostate gland ■ diabetes ■ persistent or chronic coughs such as occurs with smoking, asthma or emphysema.  
**Ask a doctor or pharmacist before use if you are taking the following drug(s)** ■ cough that occurs with a cold ■ other cough suppressants ■ other drugs containing acetaminophen.  
**When using this product do not exceed recommended dose**  
**Stop use and ask a doctor if** ■ 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 a rash or headache ■ halts. ■ These could be signs of a serious condition.  
**Keep out of reach of children.**  
**Overdose warning:** In case of overdose, get medical help or contact 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 indicate any signs or symptoms.

Made in Canada  
Distributed by:  
**JOHNSON & JOHNSON  
CONSUMER INC.**  
McNeil Consumer Healthcare Division  
Fort Washington, PA 19034 USA  
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**HERITAGE OF CARE**  
**TYLENOL**  
**HISTORY OF RELIEF**

Important: Read all product information before using. Keep this box for important information.

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

**NEW** NDC 50580-344-01

**Extra Strength**

**TYLENOL**<sup>®</sup>  
FOR ADULTS

**COLD + FLU MULTI-ACTION**

**Acetaminophen, Dextromethorphan HBr, Pseudoephedrine HCl**  
Pain Reliever-Fever Reducer, Cough Suppressant, Nasal Decongestant

**DAY NON-DROWSY**

- HEAD + BODY ACES
- FEVER + SORE THROAT
- COUGH
- NASAL CONGESTION

**24 CAPLETS** Actual Size

acetaminophen, pseudoephedrine hydrochloride, and dextromethorphan hydrobromide tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50580-344
<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	500 mg
<b>PSEUDOEPHEDRINE HYDROCHLORIDE</b> (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	30 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POWDERED CELLULOSE</b> (UNII: SMD1X3XO9M)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SODIUM STARCH GLYCOLATE TYPE A</b> (UNII: H8AV0SQX4D)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	18mm
<b>Flavor</b>		<b>Imprint Code</b>	TY;COLD;1408
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-344-01	2 in 1 CARTON	06/21/2021	
1		12 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
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**Labeler** - Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division (878046358)

Revised: 12/2021

Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division