

**EXTRA STRENGTH TYLENOL COLD PLUS FLU MULTI-ACTION DAY/NIGHT-  
acetaminophen, pseudoephedrine hydrochloride, dextromethorphan  
hydrobromide, and chlorpheniramine maleate  
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.*

-----  
**Extra Strength TYLENOL Cold + Flu Multi-Action  
Day/Night**

**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)

## **TYLENOL® COLD + FLU MULTI-ACTION NIGHT**

### **Drug Facts**

---

#### **Active ingredients (in each caplet)**

#### **Purpose**

Acetaminophen 500 mg	Pain reliever/fever reducer
Chlorpheniramine maleate 2 mg	Antihistamine
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
- cough
- nasal congestion
- sinus congestion and pressure
- sneezing and runny nose
- helps clear nasal passages
- 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)
- a breathing problem such as emphysema or chronic bronchitis
- glaucoma

**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**

- 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, FD&C blue No.1 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, powdered cellulose, pregelatinized starch, sodium starch glycolate, titanium dioxide, triacetin

## Questions or comments?

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

## PRINCIPAL DISPLAY PANEL

NEW

NDC 50580-374-01

Extra Strength

TYLENOL®

FOR ADULTS

COLD + FLU MULTI-ACTION

Acetaminophen

Dextromethorphan HBr, Pseudoephedrine HCl

Pain Reliever-Fever Reducer, Cough Suppressant, Nasal Decongestant

DAY

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

Actual Size

16 CAPLETS;

Acetaminophen

Chlorpheniramine Maleate, Dextromethorphan HBr, Pseudoephedrine HCl

Pain Reliever-Fever Reducer, Antihistamine, Cough Suppressant, Nasal Decongestant

NIGHT

- HEAD + BODY ACHES
- FEVER + SORE THROAT
- COUGH • NASAL CONGESTION
- RUNNY NOSE

Actual Size

8 CAPLETS; TOTAL 24 CAPLETS





**Important:** Read all product information before using. Keep the box for important information. Do not take the day and night caplets a total of 6 caplets in a 24-hour period. Take only as directed.

**TYLENOL® COLD + FLU MULTI-ACTION DAY**

**TYLENOL® COLD + FLU MULTI-ACTION NIGHT**

**Drug Facts**  
*(Active ingredients in each caplet)*

**Purpose**  
Acetaminophen 50mg  
Dexamethorphan HCl 1.5mg  
Cough suppressant  
Pain reliever/fever reducer  
Nasal decongestant

**Uses**  
To temporarily relieve these common cold/flu symptoms:  
■ irritated and itchy nose  
■ sinus congestion and pressure  
■ cough  
■ headache  
■ sore throat  
■ nasal congestion  
■ clear nasal passages  
■ sinus and nasal drainage  
■ temporarily reduces fever

**Warnings**  
Let 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 alcohol drinks every day while using this product  
■ or 5 or more alcohol drinks every day while using this product  
Allergy alert: acetaminophen may cause severe skin reactions. Symptoms may include:  
■ skin redness  
■ blisters  
■ rash

**Drug Facts**  
*(Active ingredients in each caplet)*

**Purpose**  
Acetaminophen 50mg  
Paraldehyde  
Antihistamine  
Cough suppressant  
Nasal decongestant

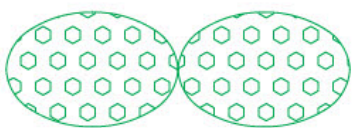
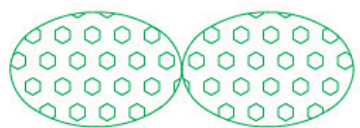
**Uses**  
To temporarily relieve these common cold/flu symptoms:  
■ minor aches and pains  
■ headache  
■ sore throat  
■ nasal congestion  
■ sinus congestion and pressure  
■ sneezing and runny nose  
■ clear nasal passages  
■ temporarily reduces fever

**Warnings**  
Let 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 alcohol drinks every day while using this product  
■ or 5 or more alcohol drinks every day while using this product  
Allergy alert: acetaminophen may cause severe skin reactions. Symptoms may include:  
■ skin redness  
■ blisters  
■ rash

LIFT HERE

**Drug Facts (continued)**  
Allergy alert: acetaminophen may cause severe skin reactions. Symptoms may include:  
■ hives  
■ rash  
If skin reaction occurs, stop use and seek medical help right away.  
Some throat warning: If some throat severe, persists for more than 2 days, 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 non-prescription). 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) for a certain drug 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 you are taking a product, 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  
■ 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 stomach phlegm (mucus)  
■ abnormal grip strength such as emphysema or traumatic brain injury  
■ glaucoma  
■ Ask a doctor or pharmacist before use if you are

**Drug Facts (continued)**  
Allergy alert: acetaminophen may cause severe skin reactions. Symptoms may include:  
■ hives  
■ rash  
If skin reaction occurs, stop use and seek medical help right away.  
Some throat warning: If some throat severe, persists for more than 2 days, 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 non-prescription). 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) for a certain drug 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 you are taking a product, 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  
■ 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 stomach phlegm (mucus)  
■ abnormal grip strength such as emphysema or traumatic brain injury  
■ glaucoma  
■ Ask a doctor or pharmacist before use if you are



# EXTRA STRENGTH TYLENOL COLD PLUS FLU MULTI-ACTION DAY/NIGHT

acetaminophen, pseudoephedrine hydrochloride, dextromethorphan hydrobromide, and chlorpheniramine maleate kit

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50580-374
---------------------	----------------	---------------------------	---------------

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-374-01	1 in 1 PACKAGE	06/21/2021	

## Quantity of Parts

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

## Part 1 of 2

### EXTRA STRENGTH TYLENOL COLD PLUS FLU MULTI-ACTION DAY

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

## Product Information

<b>Route of Administration</b>	ORAL
--------------------------------	------

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Acetaminophen</b> (UNII: 36209ITL9D) (Acetaminophen - UNII:36209ITL9D)	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: H8AV0SQQ4D)	
<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		2 in 1 CARTON		
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 final	part341	06/21/2021	

## Part 2 of 2

### EXTRA STRENGTH TYLENOL COLD PLUS FLU MULTI-ACTION NIGHT

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

### Product Information

<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>Chlorpheniramine Maleate</b> (UNII: V1Q0O9OJ9Z) (Chlorpheniramine - UNII:3U6IO1965U)	Chlorpheniramine Maleate	2 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>FD&amp;C Blue No. 1 Aluminum Lake</b> (UNII: J9EQA3S2JM)	
<b>hypromellose, unspecified</b> (UNII: 3NXW29V3WO)	
<b>magnesium stearate</b> (UNII: 70097M6I30)	
<b>microcrystalline cellulose</b> (UNII: OP1R32D61U)	
<b>polydextrose</b> (UNII: VH2XOU12IE)	
<b>propylene glycol</b> (UNII: 6DC9Q167V3)	
<b>powdered cellulose</b> (UNII: SMD1X3XO9M)	
<b>sodium starch glycolate type A</b> (UNII: H8AV0SQX4D)	
<b>titanium dioxide</b> (UNII: 15FIX9V2JP)	
<b>triacetin</b> (UNII: XHX3C3X673)	

## Product Characteristics

<b>Color</b>	BLUE	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	18mm
<b>Flavor</b>		<b>Imprint Code</b>	TY;COLD;1407
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		2 in 1 CARTON		
1		4 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 final	part341		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/21/2021	

**Labeler** - Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division (878046358)