# TYLENOL COLD AND FLU- acetaminphen tablet, film coated R J General Corporation

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#### TYLENOL ® COLD AND FLU

#### **Drug Facts**

Active ingredients (in each caplet)	Purpose
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

#### Uses

- for the temporary relief of the following cold/flu symptoms:
  - minor aches and pains
  - headache
  - sore throat
  - nasal congestion
  - cough
- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive
- temporarily reduces fever

### Warnings

### Liver warning

This product contains acetaminophen. The maximum daily dose of this product is 10 caplets (3,250 mg acetaminophen) in 24 hours. 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, chronic bronchitis 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> <li>take 2 caplets every 4 hours</li> <li>swallow whole; do not crush, chew or dissolve</li> <li>do not take more than 10 caplets in 24 hours</li> </ul>
children under 12 years	ask a doctor

#### Other information

- each caplet contains: sodium 3 mg
- store between 20-25°C (68-77°F)
- do not use if pouch is torn or damaged

#### **Inactive ingredients**

carnauba wax, croscarmellose sodium, D&C yellow no. 10 aluminum lake, flavor, hydroxypropyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, pregelatinized starch, sucralose, titanium dioxide

#### Questions or comments?

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

Made in Italy

#### Distributed by:

JOHNSON & JOHNSON CONSUMER INC. McNeil Consumer Healthcare Division Fort Washington, PA 19034 USA

#### Repackaged and distributed by:

RJ General 2024 Northwest Drive Cincinnati OH 45231

### PRINCIPAL DISPLAY PANEL - 100 Caplet Pouch Box

TYLENOL ® FOR ADULTS

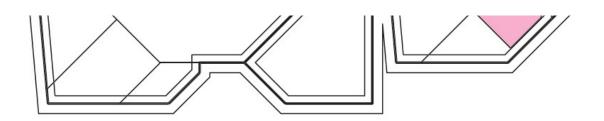
#### COLD + FLU SEVERE

Acetaminophen, Dextromethorphan HBr, Phenylephrine HCl, Guaifenesin Pain Reliever-Fever Reducer, Cough Suppressant, Nasal Decongestant, Expectorant

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

50 Pouches of 2 Caplets each





\$99£-\$68-\(\alpha\) HOW CAN WE help?



Active ingredients (in each caplet) Acetaminophen 325 mg...... Dectromethorphan HBr 10 mg.. Guaifenesin 200 mg... Phanylephrine HCl 5 mg....

...Cough suppressan .......Expectoran

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Other information

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Inactive ingredients

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Distributed by: JOHNSON & JOHNSON CONSUMER INC.

McNeil Consumer Healthcare Division Fort Washington, PA 19034 USA @1&1CI 2021

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Repackaged and distributed by: Cincinnati OH 45231

PARENTS:

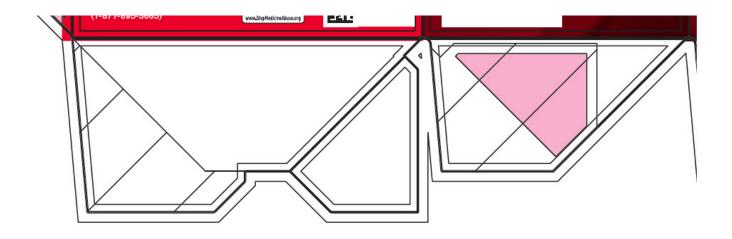




Acetaminophen, Dextromethorphan HBr, Phenylephrine HCl, Gualfenesin Pain Reliever-Fever Reducer, Cough Suppressant, Nasal Decongestant, Expectorant







## **TYLENOL COLD AND FLU**

acetaminphen tablet, film coated

<b>Product Information</b>			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70264-025(NDC:50580-402)
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS 297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg	

Inactive Ingredients	
Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)	
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	yellow	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	TYLENOL;SEVERE
Contains			

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:70264-025- 02	50 in 1 BOX	05/01/2021			
1		2 in 1 POUCH; 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	05/01/2021		

# Labeler - R J General Corporation (122542830)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
R J General Corporation		122542830	repack(70264-025)	

Establishment				
Name	Address	ID/FEI	Business Operations	
Johnson & Johnson		878046358	manufacture(70264-025)	

Revised: 10/2023 R J General Corporation