

**TYLENOL COLD PLUS FLU SEVERE AND TYLENOL COLD MAX COPACK-  
acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, guaifenesin, and  
phenylephrine hydrochloride**

**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.*

**TYLENOL Cold + Flu Severe and TYLENOL COLD MAX LIQUID CoPack**

**TYLENOL Cold + Flu Severe**

***Drug Facts***

<b><i>Active ingredients (in each 15 mL)</i></b>	<b><i>Purpose</i></b>
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

**Uses**

- temporarily relieves 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. 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)**
- 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 4 hours while symptoms last
- do not take more than 150 mL in 24 hours, unless directed by a

	doctor
children under 12 years	ask a doctor

**Other information**

- **each 15 mL contains:** sodium 5 mg
- store between 20-25°C (68-77°F). Do not refrigerate.
- **do not use if neck band imprinted with "TYLENOL COLD + FLU SEVERE" or foil inner seal imprinted with "SAFETY SEAL®" is broken or missing**

**Inactive ingredients**

anhydrous citric acid, FD&C blue no. 1, FD&C red no. 40, FD&C yellow no. 6, flavors, glycerin, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucralose

**Questions or comments?**

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

**TYLENOL COLD MAX NIGHT**

***Drug Facts***

<b><i>Active ingredients (in each 15 mL)</i></b>	<b><i>Purpose</i></b>
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Doxylamine succinate 6.25 mg	Antihistamine
Phenylephrine HCl 5 mg	Nasal decongestant

**Uses**

- temporarily relieves these common cold/flu symptoms:
  - minor aches and pains
  - headache
  - sore throat
  - nasal congestion
  - runny nose and sneezing
  - cough
  - sinus congestion and pressure
- helps clear nasal passages
- relieves cough to help you sleep
- 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
- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- 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**

- 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)**
- 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	<ul style="list-style-type: none"> <li>▪ take 30 mL in the dosing cup provided every 4 hours while symptoms last</li> <li>▪ do not take more than 150 mL in 24 hours, unless directed by a doctor</li> </ul>
children under 12 years	ask a doctor

### Other information

- **each 15 mL contains:** sodium 5 mg
- store between 20-25°C (68-77°F). Do not refrigerate.
- **do not use if neck band imprinted with "TYLENOL COLD MAX" or foil inner seal imprinted with "SAFETY SEAL®" is broken or missing**

### Inactive ingredients

alcohol, anhydrous citric acid, FD&C blue no. 1, flavor, glycerin, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucralose

### Questions or comments?

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

### PRINCIPAL DISPLAY PANEL

**DAYTIME**

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

Warming  
HONEY  
LEMON

8 Fl OZ (240mL)

**NIGHTTIME**

NDC 50580-231-01

TYLENOL®  
FOR ADULTS

COLD MAX

Acetaminophen, Dextromethorphan HBr, Doxylamine Succinate, Phenylephrine HCl  
Pain Reliever--Fever Reducer, Cough Suppressant, Antihistamine, Nasal Decongestant

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

COOL  
BURST®

Alcohol 0.7%

8 Fl OZ (240mL)

9/16

PART #

2

19/32

8 1/2

2 1/4



DAYTIME



DAYTIME



NIGHTTIME

# TYLENOL<sup>®</sup>

FOR ADULTS  
**COLD + FLU SEVERE**

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

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



8 FL OZ (240mL)

# TYLENOL<sup>®</sup>

FOR ADULTS  
**COLD + FLU SEVERE**

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

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



8 FL OZ (240mL)

# TYLENOL<sup>®</sup>

FOR ADULTS  
**COLD MAX**

Acetaminophen, Dextromethorphan HBr, Oxycodone Hydrochloride, Pseudoephedrine HCl  
Pain Reliever-Fever Reducer, Cough Suppressant, Antitussive, Nasal Decongestant

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



Alcohol 0.7% 8 FL OZ (240mL)

NDC 51990-235-01

Important: Read all product information before using. Do not take Day and Night liquids at the same time. Take only as directed.

Distributed by:  
**JOHNSON & JOHNSON CONSUMER INC.**  
McNeil Consumer Healthcare Division  
Fort Washington, PA 19034 USA  
©Johnson & Johnson Consumer Inc, 2018  
MCN-TY-0587

COPY

2 1/32



OPEN TO READ DRUG FACTS

**TYLENOL<sup>®</sup>**  
COLD + FLU SEVERE

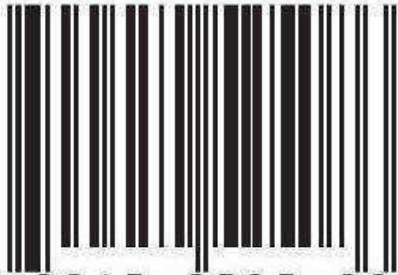


OPEN TO READ DRUG FACTS (Warnings, Directions...) → PEEL

30042162

Do not use if neck band imprinted with "TYLENOL COLD + FLU SEVERE" or foil inner seal imprinted with "SAFETY SEAL®" is broken or missing.

**DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN**



3 0045-0525-08 6

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

SNAP THIS CODE OR TEXT TYCOLD4 TO 87715

MSG & DATA RATES MAY APPLY. TEXT HELP FOR HELP. TEXT STOP FOR STOP.



Acetaminophen (325 mg per 15 mL)  
Dextromethorphan HBr (10 mg per 15 mL)  
Phenylephrine HCl (5 mg per 15 mL)  
Guaifenesin (200 mg per 15 mL)

8 fl oz (240 mL)

Made In Canada

Distributed by:  
**JOHNSON & JOHNSON CONSUMER INC.**  
McNeil Consumer Healthcare Division  
Fort Washington, PA 19034 USA

© J&JCI 2018

30042162

### Drug Facts

**Active ingredients (in each 15 mL)**      **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

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

### Drug Facts (continued)

- 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

### Drug Facts (continued)

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

### Drug Facts (continued)

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

### Drug Facts (continued)

- 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

### Drug Facts (continued)

- 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.



### Drug Facts (continued)

#### Directions

- do not take more than directed (see overdose warning)
- 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	<ul style="list-style-type: none"> <li>take 30 mL in the dosing cup provided every 4 hours while symptoms last</li> <li>do not take more than 150 mL in 24 hours, unless directed by a doctor</li> </ul>
children under 12 years	ask a doctor

### Drug Facts (continued)

#### Other information

- each 15 mL contains: sodium 5 mg
- store between 20-25°C (68-77°F). Do not refrigerate.
- do not use if neck band imprinted with "TYLENOL COLD + FLU SEVERE" or foil inner seal imprinted with "SAFETY SEAL®" is broken or missing

#### Inactive ingredients

anhydrous citric acid, FD&C blue no. 1, FD&C red no. 40, FD&C yellow no. 6, flavors, glycerin, propylene glycol, purified water, sodium benzoate,

any signs or symptoms.

### Drug Facts (continued)

sorbitol solution, sucralose

#### Questions or comments?

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

**PARENTS:**

Learn about teen medicine abuse

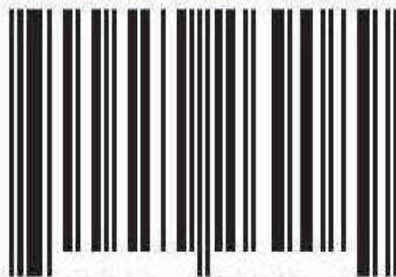
[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)

OPEN TO READ DRUG FACTS (Warnings, Directions...)

PEEL

30042166 Do not use if neck band imprinted with "TYLENOL COLD MAX" or foil inner seal imprinted with "SAFETY SEAL®" is broken or missing.

**DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN**



3 0045-0269-08 9

**TYLENOL**  
COLD MAX

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

SNAP THIS CODE OR TEXT TYCOLD7 TO 87715

MSG & DATA RATES MAY APPLY  
TEXT HELP FOR HELP  
TEXT STOP FOR STOP



Acetaminophen (325 mg per 15 mL)  
Dextromethorphan HBr (10 mg per 15 mL)  
Doxylamine succinate (6.25 mg per 15 mL)  
Phenylephrine HCl (5 mg per 15 mL)

8 fl oz (240 mL)

Made In Canada

Distributed by:  
**JOHNSON & JOHNSON CONSUMER INC.**  
McNeil Consumer Healthcare Division  
Fort Washington, PA 19034 USA  
© J&JCI 2018

30042166

### Drug Facts

#### Active ingredients Purpose (in each 15 mL)

Acetaminophen 325 mg ..... Pain reliever/fever reducer  
Dextromethorphan HBr 10 mg ..... Cough suppressant  
Doxylamine succinate 6.25 mg ..... Antihistamine  
Phenylephrine HCl 5 mg ..... Nasal decongestant

#### Uses

- temporarily relieves these common cold/flu symptoms:
  - minor aches and pains

### Drug Facts (continued)

- helps clear nasal passages
- relieves cough to help you sleep
- 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

### Drug Facts (continued)

- 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



- headache
- sore throat
- nasal congestion
- runny nose and sneezing
- cough
- sinus congestion and pressure

- 3 or more alcoholic drinks every day while using this product
- Allergy alert:** acetaminophen may cause severe skin reactions. Symptoms may include:
- skin reddening

- 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

### Drug Facts (continued)

- 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

### Drug Facts (continued)

- prostate gland
- a breathing problem such as emphysema or chronic bronchitis
  - glaucoma
  - 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,

### Drug Facts (continued)

- 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

### Drug Facts (continued)

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)
- mL = milliliter
- use only enclosed dosing cup

### Drug Facts (continued)

designed for use with this product. Do not use any other dosing device.

- |                                       |  |
|---------------------------------------|--|
| adults and children 12 years and over | <ul style="list-style-type: none"> <li>■ take 30 mL in the dosing cup provided every 4 hours while symptoms last</li> <li>■ do not take more than 150 mL in 24 hours, unless directed by a doctor</li> </ul> |
| children under 12 years               | ask a doctor   |

### Other information

- each 15 mL contains: sodium 5 mg
- store between 20-25°C (68-77°F). Do not refrigerate.
- do not use if neck band imprinted with "TYLENOL COLD MAX" or

### Drug Facts (continued)

foil inner seal imprinted with "SAFETY SEAL®" is broken or missing

### Inactive ingredients

alcohol, anhydrous citric acid, FD&C blue no. 1, flavor, glycerin, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucralose

### Questions or comments?

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

**PARENTS:**

Learn about teen medicine abuse

[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)

## TYLENOL COLD PLUS FLU SEVERE AND TYLENOL COLD MAX COPACK

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, guaifenesin, and phenylephrine hydrochloride kit

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:50580-231

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-231-01	1 in 1 PACKAGE	08/20/2018	

## Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	2 BOTTLE, PLASTIC	480 mL
Part 2	1 BOTTLE, PLASTIC	240 mL

## Part 1 of 2

### TYLENOL COLD PLUS FLU SEVERE

acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride solution

## Product Information

Item Code (Source)	NDC:50580-403
Route of Administration	ORAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Acetaminophen (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)	Acetaminophen	325 mg in 15 mL
Dextromethorphan Hydrobromide (UNII: 9D2RT9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	Dextromethorphan Hydrobromide	10 mg in 15 mL
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	200 mg in 15 mL
Phenylephrine Hydrochloride (UNII: 04JA59TNSJ) (Phenylephrine - UNII:1WS297W6MV)	Phenylephrine Hydrochloride	5 mg in 15 mL

## Inactive Ingredients

Ingredient Name	Strength
anhydrous citric acid (UNII: XF417D3PSL)	
FD&C blue no. 1 (UNII: H3R47K3TBD)	
FD&C red no. 40 (UNII: WZB9127XOA)	
FD&C yellow no. 6 (UNII: H77VEI93A8)	
glycerin (UNII: PDC6A3C0OX)	
propylene glycol (UNII: 6DC9Q167V3)	
water (UNII: 059QF0KO0R)	
sodium benzoate (UNII: OJ245FE5EU)	
sorbitol (UNII: 506T60A25R)	
sucralose (UNII: 96K6UQ3ZD4)	

## Product Characteristics

<b>Color</b>	BROWN, YELLOW (Amber colored)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	HONEY, LEMON	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-403-08	240 mL in 1 BOTTLE, PLASTIC; Type 1: Convenience Kit of Co-Package		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	07/05/2010	

## Part 2 of 2

### TYLENOL COLD MAX NIGHT

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, and phenylephrine hydrochloride solution

## Product Information

<b>Item Code (Source)</b>	NDC:50580-571
<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 in 15 mL
<b>Dextromethorphan Hydrobromide</b> (UNII: 9D2RT9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	Dextromethorphan Hydrobromide	10 mg in 15 mL
<b>Doxylamine Succinate</b> (UNII: V9B19B5YI2) (Doxylamine - UNII:95QB77JKPL)	Doxylamine Succinate	6.25 mg in 15 mL
<b>Phenylephrine Hydrochloride</b> (UNII: 04JA59TNSJ) (Phenylephrine - UNII:1WS297W6MV)	Phenylephrine Hydrochloride	5 mg in 15 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>alcohol</b> (UNII: 3K9958V90M)	
<b>anhydrous citric acid</b> (UNII: XF417D3PSL)	
<b>FD&amp;C blue no. 1</b> (UNII: H3R47K3TBD)	

<b>glycerin</b> (UNII: PDC6A3C0OX)	
<b>propylene glycol</b> (UNII: 6DC9Q167V3)	
<b>water</b> (UNII: 059QF0KO0R)	
<b>sodium benzoate</b> (UNII: OJ245FE5EU)	
<b>sorbitol</b> (UNII: 506T60A25R)	
<b>sucralose</b> (UNII: 96K6UQ3ZD4)	

<b>Product Characteristics</b>			
<b>Color</b>	BLUE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	BERRY, MINT (cooling berry mint flavored)	<b>Imprint Code</b>	
<b>Contains</b>			

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-571-01	240 mL in 1 BOTTLE, PLASTIC; Type 1: Convenience Kit of Co-Package		

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	04/13/2015	

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	08/20/2018	

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