LIL DRUG STORE TYLENOL COLD PLUS FLU SEVERE- acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet, film coated

TYLENOL COLD PLUS FLU SEVERE, CVP HEALTH- acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet, film coated

TYLENOL COLD PLUS FLU SEVERE, TRAVEL BASIX- acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet, film coated

TYLENOL COLD PLUS FLU SEVERE, LIL DRUG STORE- acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet, film coated

Lil Drug Store Products, Inc

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Tylenol <sup>®</sup> Cold + Flu Severe, Lil' Drug Store <sup>®</sup>, CVP <sub>®</sub> HEALTH, TRAVEL BASIX

## **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)

# Product distributed by: JOHNSON & JOHNSON CONSUMER INC.

McNeil Consumer Healthcare Division, Fort Washington, PA 19034 USA

**Repackaged and distributed by:** Lil' Drug Store Products, Inc., 9300 Earhart Lane SW

Cedar Rapids, IA 52402

# **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

# 6

# **Caplets**

3 POUCHES OF 2 CAPLETS EACH

# Lil

**Drug Store** ®



Caplets

#### DO NOT USE IF POUCH IS TORN OR DAMAGED

#### **Drug Facts**

Active ingredients (in each caplet)

Purpose

Dextromethorphan HBr 10 mg.. Guaifenesin 200 mg.... .Cough suppressant .....Expectorant Phenylephrine HCI 5 mg Nasal decongestant

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

#### 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.

LIFT PANEL FOR CONTINUED DRUG FACTS

## stalgsD 8

# COTD + LTN SENES

#### 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.
- 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 neart disease
- high blood pressure thyroid disease
- 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

#### 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
- 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.

# **LATENOT**

#### Drug Facts (continued)

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

#### Directions

#### m do not take more than directed (see overdose warning)

adults and children 12 years and over

■ take 2 caplets every 4 hours ■ swallow whole; do not crush, chew or dissolve do not take more than 10 caplets in 24 hours

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 camauba wax, croscarmellose sodium, D&C yellow no. 10 aluminum lake, flavor, hydroxypropyl cellulose, hypromello 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, Product distributed by: JOHNSON & JOHNSON CONSUMER INC. McNeil Consumer Healthcare Division, Fort Washington, PA 19034 USA ©J&JCI 2016 Visit us at www.tylenol.com or call toll-free 1-877-TYLENOL (1-877-895-3665)

Repackaged and distributed by: Lil' Drug Store Products, Inc., 9300 Earhart Lane SW Cedar Rapids. IA 52404 1-877-507-6516 (M-F 8AM-4:30PM CST) www.lildrugstore.com 97563C-US-02-17-A



PARENTS:
Learn about teen modicine abuse
www.StopMedicineAbuse.org

Caplets

# Tylenol Cold + Flu SEVERE, CVP ® Health 4ct - PDP/Package

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

[caplets image]

# 4

# Caplets

2 POUCHES OF 2 CAPLETS EACH

[CVP HEALTH logo]



Tylenol ® Cold + Flu Severe, 25ct, Lil' Drug Store ® - PDP/Package

TYLENOL ®

**FOR ADULTS** 

Cold + Flu Severe

**Acetaminophen**, Dextromethorphan HBr, Phenylephrine HCI, Guaifenesin Pain Reliever–Fever Reducer, Cough Suppressant, Nasal Decongestant, Expectorant

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

#### MUCUS + CHEST CONGESTION

[caplets (2) image]

# 25 Pouches of 2 Caplets each

[Lil' Drug Store logo]



# Tylenol Cold + Flu SEVERE, TRAVEL BASIX 4ct - PDP/Package

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

[caplets image]

4

# Caplets

2 POUCHES OF 2 CAPLETS EACH

## [TRAVEL BASIX logo]



Tylenol  $^{\$}$  Cold + Flu Severe, 30ct, Lil' Drug Store  $^{\$}$  - PDP/Package TYLENOL  $^{\$}$ 

**FOR ADULTS** 

Cold + Flu Severe

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

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

[caplets (2) image]

30 Pouches of 2 Caplets each

[Lil' Drug Store ® logo]



# LIL DRUG STORE TYLENOL COLD PLUS FLU SEVERE

acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet, film coated

<b>Product Information</b>			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66715-9756
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	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: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients	
Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
ALUMINUM OXIDE (UNII: LMI26O6933)	

HYDROXYPROPYL CELLULOSE (70000 WAMW) (UNII: 6607AQV0RT)
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)
MAGNESIUM STEARATE (UNII: 70097M6I30)
CARNAUBA WAX (UNII: R12CBM0EIZ)
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)
STARCH, CORN (UNII: O8232NY3SJ)
SUCRALOSE (UNII: 96K6UQ3ZD4)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

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

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66715- 9756-2	2 in 1 CARTON	10/23/2017	
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:66715- 9756-3	3 in 1 CARTON	08/15/2019	
2		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	10/23/2017	

# TYLENOL COLD PLUS FLU SEVERE, CVP HEALTH

acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66715-6556
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	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: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients	
Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
HYDROXYPROPYL CELLULOSE (70000 WAMW) (UNII: 6607AQV0RT)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STARCH, CORN (UNII: O8232NY3SJ)	
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:66715- 6556-2	2 in 1 CARTON	05/06/2022		
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	05/06/2022	

# **TYLENOL COLD PLUS FLU SEVERE, TRAVEL BASIX**

acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet, film coated

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66715-7856	
Route of Administration	ORAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	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: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg		

Inactive Ingredients	
Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
HYDROXYPROPYL CELLULOSE (70000 WAMW) (UNII: 6607AQV0RT)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STARCH, CORN (UNII: 08232NY3SJ)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

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

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66715- 7856-2	2 in 1 CARTON	11/30/2022	
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	11/30/2022	

# TYLENOL COLD PLUS FLU SEVERE, LIL DRUG STORE

acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet, film coated

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66715-6456	
Route of Administration	ORAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	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: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg		

Inactive Ingredients			
Ingredient Name	Strength		
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)			
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)			
ALUMINUM OXIDE (UNII: LMI26O6933)			
HYDROXYPROPYL CELLULOSE (70000 WAMW) (UNII: 6607AQV0RT)			
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
CARNAUBA WAX (UNII: R12CBM0EIZ)			
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
STARCH, CORN (UNII: O8232NY3SJ)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			

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

# **Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66715- 6456-7	25 in 1 CARTON	04/19/2022	
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:66715- 6456-8	30 in 1 CARTON	04/19/2022	
2		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	04/19/2022			

# Labeler - Lil Drug Store Products, Inc (093103646)

Revised: 7/2024 Lil Drug Store Products, Inc