

TYLENOL COLD PLUS FLU SEVERE- acetaminophen, dextromethorphan hbr, phenylephrine hcl, guaifenesin tablet
TYLENOL COLD PLUS FLU SEVERE- acetaminophen, dextromethorphan hbr, phenylephrine hcl, guaifenesin tablet
Lil' Drug Store Products, Inc.

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

Drug Facts

Drug Facts

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

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

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

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.

Keep out of reach of children.

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">• take 2 caplets every 4 hours• swallow whole; do not crush, chew or dissolve• do not take more than 10 caplets in 24 hours
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 blister unit is torn or broken**

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)

Active Ingredient (in each tablet)

Purpose

Active ingredients (in each caplet)

Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Guaifenesin 200 mg
Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer
Cough suppressant
Expectorant
Nasal decongestant

PRINCIPAL DISPLAY PANEL 4ct 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

2 Pouches of 2 Caplets each



TYLENOL®
FOR ADULTS

COLD + FLU SEVERE

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

HERITAGE OF CARE
TYLENOL
HISTORY OF RELIEF

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

2 Pouches of 2 Caplets each

PRINCIPAL DISPLAY PANEL 25ct 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

25 Pouches of 2 Caplets each

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



25 Pouches of 2 Caplets each

PRINCIPAL DISPLAY PANEL 30ct 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

30 Pouches of 2 Caplets each



CVP 4 Count Carton

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

4 Caplets

2 Pouches of 2 Caplets each

CVP

HEALTH



TYLENOL COLD PLUS FLU SEVERE

acetaminophen, dextromethorphan hbr,phenylephrine hcl, guaifenesin tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:29485-8062
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (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
HYDROXYPROPYL CELLULOSE (70000 WAMW) (UNII: 66O7AQV0RT)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
ALUMINUM OXIDE (UNII: LMI26O6933)	

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:29485-8062-3	30 in 1 BOX	08/22/2017	
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:29485-8062-2	25 in 1 BOX	07/10/2020	

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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 final	M012	08/22/2017	

TYLENOL COLD PLUS FLU SEVERE

acetaminophen, dextromethorphan hbr,phenylephrine hcl, guaifenesin tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:29485-8060
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (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
HYDROXYPROPYL CELLULOSE (70000 WAMW) (UNII: 66O7AQV0RT)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	

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:29485-8060-4	2 in 1 PACKAGE	04/18/2017	
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 final	M012	04/18/2017	

TYLENOL COLD PLUS FLU SEVERE

acetaminophen, dextromethorphan hbr,phenylephrine hcl, guaifenesin tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:29485-6556
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (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
HYDROXYPROPYL CELLULOSE (70000 WAMW) (UNII: 66O7AQV0RT)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
STARCH, CORN (UNII: O8232NY3SJ)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
ALUMINUM OXIDE (UNII: LMI26O6933)	

CROSCARMELOSE SODIUM (UNII: M28OL1HH48)

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:29485-6556-4	2 in 1 CARTON	08/25/2017	
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 final	M012	08/25/2017	

Labeler - Lil' Drug Store Products, Inc. (093103646)

Revised: 7/2023

Lil' Drug Store Products, Inc.