TYLENOL COLD PLUS FLU SEVERE DAY/NIGHT- acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride
Johnson & Johnson Consumer Inc.

TYLENOL ® COLD + FLU SEVERE NIGHT

Drug Facts

Active ingredients (in each caplet)	***Purpose***
Acetaminophen 325 mg	Pain reliever/fever reducer
Chlorpheniramine maleate 2 mg	Antihistamine
Dextromethorphan HBr 10 mg	Cough suppressant
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
  - sinus congestion and pressure
  - sneezing and runny nose
- helps clear nasal passages
- relieves cough to help you sleep
- 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 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	▪ 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

- store between 20-25°C (68-77°F)
- **do not use if blister unit is torn or broken**

Inactive ingredients

anhydrous citric acid, carnauba wax, FD&C blue no. 1 aluminum lake, flavor, hypromellose, magnesium stearate, microcrystalline cellulose, modified starch, polyethylene glycol, polysorbate 80, potassium sorbate, powdered cellulose, pregelatinized starch, sodium benzoate, sodium citrate dihydrate, sodium starch glycolate, sucralose, titanium dioxide

Questions or comments?

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

TYLENOL ® COLD + FLU SEVERE DAY

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	▪ take 2 caplets every 4 hours ▪ swallow whole; do not crush, chew or

adults and children 12 years and over	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)

PRINCIPAL DISPLAY PANEL

NDC 50580-414-04

TYLENOL ®
FOR ADULTS

COLD + FLU
SEVERE

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

DAY

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

Actual
Size

16 CAPLETS

Acetaminophen,
Chlorpheniramine Maleate,
Dextromethorphan HBr, Phenylephrine HCl
Pain Reliever–Fever Reducer, Antihistamine,
Cough Suppressant, Nasal Decongestant

NIGHT

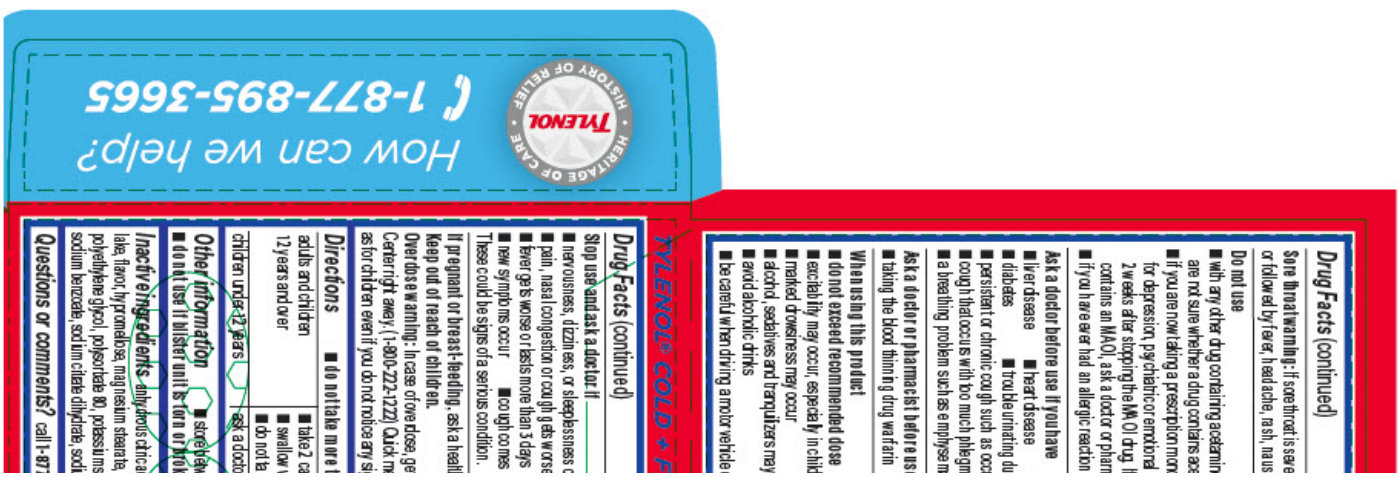
- HEAD + BODY ACHES
- FEVER + SORE THROAT
- COUGH
- NASAL CONGESTION
- RUNNY NOSE

Actual
Size

8 CAPLETS

TOTAL 24 CAPLETS


123665
NDC 50580-414-04
TYLENOL®
FOR ADULTS
COLD + FLU
SEVERE
Acetaminophen,
Dextromethorphan HBr,
Phenylephrine HCl, Guaifenesin
Pain Reliever–Fever Reducer, Cough Suppressant,
Nasal Decongestant, Expectorant
Acetaminophen,
Chlorpheniramine Maleate,
Dextromethorphan HBr, Phenylephrine HCl
Pain Reliever–Fever Reducer, Antihistamine,
Cough Suppressant, Nasal Decongestant
DAY
• HEAD + BODY ACHES
• FEVER + SORE THROAT
• COUGH
• NASAL CONGESTION
• MUCUS + CHEST CONGESTION
Actual Size
16 CAPLETS
NIGHT
• HEAD + BODY ACHES
• FEVER + SORE THROAT
• COUGH
• NASAL CONGESTION
• RUNNY NOSE
Actual Size
8 CAPLETS
TOTAL 24 CAPLETS
PARENTS:
Learn about teen medicine abuse
www.StopMedicineAbuse.org
DO NOT USE IF BLISTER UNIT IS TORN OR BROKEN
30047050/
123665


How can we help?
1-877-895-3665
HISTORY OF RELIEF
TYLENOL
HERITAGE OF CARE
Drug Facts (continued)
Sore throat warning: if sore throat is seve
or followed by fever, headache, rash, na
Do not use
■ with any other drug containing acetamin
are not sure whether a drug contains ace
■ if you are now taking a prescription mon
for depression, psychiatric or emotional
2 weeks after stopping the MAOI drug. I
contains an MAOI, ask a doctor or pharm
■ if you have ever had an allergic reaction
Ask a doctor before use if you have
■ liver disease ■ heart disease
■ diabetes ■ trouble urinating du
■ persistent or chronic cough such as occ
■ cough that occurs with too much phlegm
■ a breathing problem such as emphysem
Ask a doctor or pharmacist before us
■ taking the blood thinning drug warfarin
When using this product
■ do not exceed recommended dose
■ excitability may occur, especially in child
■ marked drowsiness may occur
■ alcohol, sedatives and tranquilizers may
■ avoid alcoholic drinks
■ be careful when driving a motor vehicle
Drug Facts (continued)
Stop use and ask a doctor if
■ nervousness, dizziness, or sleeplessness c
■ pain, nasal congestion or cough gets worse
■ fever gets worse or lasts more than 3 days
■ new symptoms occur ■ cough comes
These could be signs of a serious condition.
If pregnant or breast-feeding, ask a healt
Keep out of reach of children.
Overdose warning: In case of overdose, ge
Call a doctor right away. (1-800-222-1222) Quick m
as for children even if you do not notice any si
Directions ■ do not take more t
adults and children ■ take 2 ca
12 years and over ■ swallow
■ do not ta
children under 12 years ask a doctor
Other information ■ store at
■ do not use if blister unit is torn or bro
Inactive ingredients anhydrous citric a
lake, flavor, hypromellose, magnesium stearate,
polyethylene glycol, polysorbate 80, potassium
sodium benzoate, sodium citrate dihydrate, sodi
Questions or comments? call 1-87

TYLENOL COLD PLUS FLU SEVERE DAY/NIGHT

acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50580-414

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:50580-414-03	3 in 1 CELLO PACK	07/18/2016	
1	NDC:50580-414-04	1 in 1 CARTON; Type 1: Convenience Kit of Co-Package		
2	NDC:50580-414-04	1 in 1 CARTON	12/21/2018	

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

Part 1 of 2

TYLENOL COLD PLUS FLU SEVERE NIGHT

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

Product Information	
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients	
Ingredient Name	**Strength**
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	

POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

Product Characteristics

Color	blue (Light blue)	**Score**	no score
Shape	OVAL	**Size**	18mm
Flavor		**Imprint Code**	TYLENOL;1075
Contains			

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 Drug	M012		

Part 2 of 2

TYLENOL COLD PLUS FLU SEVERE

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

Product Information

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
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: 3WQ0SDW1A)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
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		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 Drug	M012	09/01/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	07/18/2016	

Labeler - Johnson & Johnson Consumer Inc. (878046358)

Revised: 1/2024 Johnson & Johnson Consumer Inc.