EXTRA STRENGTH TYLENOL COLD PLUS FLU MULTI-ACTION DAY/NIGHT- acetaminophen, pseudoephedrine hydrochloride, dextromethorphan hydrobromide, and chlorpheniramine maleate
Johnson & Johnson Consumer Inc.

Extra Strength TYLENOL Cold + Flu Multi-Action

Day/Night

TYLENOL® COLD + FLU MULTI-ACTION DAY

Drug Facts

Active ingredients (in each caplet)	***Purpose***
Acetaminophen 500 mg	Pain reliever/fever reducer
Dextromethorphan HBr 15 mg	Cough suppressant
Pseudoephedrine HCl 30 mg	Nasal decongestant

Uses

- temporarily relieves these common cold/flu symptoms:
  - minor aches and pains
  - headache
  - sore throat
  - nasal congestion
  - cough
  - sinus congestion and pressure
- helps clear nasal passages
- promotes nasal and sinus drainage
- 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 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	▪ take 2 caplets every 6 hours while symptoms last ▪ do not take more than 6 caplets in 24 hours, unless directed by a doctor ▪ do not use for more than 10 days unless directed by a doctor
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

carnauba wax, hypromellose, magnesium stearate, microcrystalline cellulose, powdered cellulose, pregelatinized starch, propylene glycol, sodium starch glycolate, titanium dioxide

Questions or comments?

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

TYLENOL® COLD + FLU MULTI-ACTION NIGHT

Drug Facts

Active ingredients (in each caplet)	***Purpose***
Acetaminophen 500 mg	Pain reliever/fever reducer
Chlorpheniramine maleate 2 mg	Antihistamine
Dextromethorphan HBr 15 mg	Cough suppressant
Pseudoephedrine HCl 30 mg	Nasal decongestant

Uses

- temporarily relieves these common cold/flu symptoms:
  - minor aches and pains
  - headache
  - sore throat
  - cough

- nasal congestion
- sinus congestion and pressure
- sneezing and runny nose
- helps clear nasal passages
- 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 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 6 hours while symptoms last ▪ do not take more than 6 caplets in 24 hours, unless directed by a doctor ▪ do not use for more than 10 days unless directed by a doctor
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

carnauba wax, FD&C blue No.1 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, powdered cellulose, pregelatinized starch, sodium starch glycolate, titanium dioxide, triacetin

Questions or comments?

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

PRINCIPAL DISPLAY PANEL

NDC 50580-374-01

Extra Strength
TYLENOL ®

FOR ADULTS

COLD + FLU MULTI-ACTION

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

DAY

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

Actual Size

16 CAPLETS;

Acetaminophen
Chlorpheniramine Maleate, Dextromethorphan HBr, Pseudoephedrine 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

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

30051444

NDC 50580-374-01

Extra Strength

TYLENOL®

FOR ADULTS

COLD + FLU MULTI-ACTION

Acetaminophen

Dextromethorphan HBr, Pseudoephedrine HCl

Pain Reliever-Fever Reducer, Cough Suppressant, Nasal Decongestant

DAY

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

Actual Size

16 CAPLETS;

Acetaminophen

Chlorpheniramine Maleate, Dextromethorphan HBr, Pseudoephedrine 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

Extra Strength TYLENOL® COLD + FLU MULTI-ACTION

DO NOT USE IF BLISTER UNIT IS TORN OR BROKEN.

Made in Canada

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

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

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EPD 12762

EPD 12762

TYLENOL® COLD + FLU MULTI-ACTION DAY

Drug Facts (continued)

- 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 6 hours while symptoms last ■ do not take more than 6 caplets in 24 hours, unless directed by a doctor ■ do not use for more than 10 days unless directed by a doctor
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 carnauba wax, hypromellose, magnesium stearate, microcrystalline cellulose, powdered cellulose, pregelatinized starch, propylene glycol, sodium starch glycolate, titanium dioxide

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

TYLENOL® COLD + FLU MULTI-ACTION NIGHT

Drug Facts (continued)

- 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.

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Other information

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

Inactive ingredients carnauba wax, FD&C blue No. 1 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, powdered cellulose, pregelatinized starch, sodium starch glycolate, titanium dioxide, triacetin

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

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 ▼
■ nervousness, dizziness, or sleeplessness occur
■ fever gets worse or lasts more than 3 days

Ask a doctor before use if you have

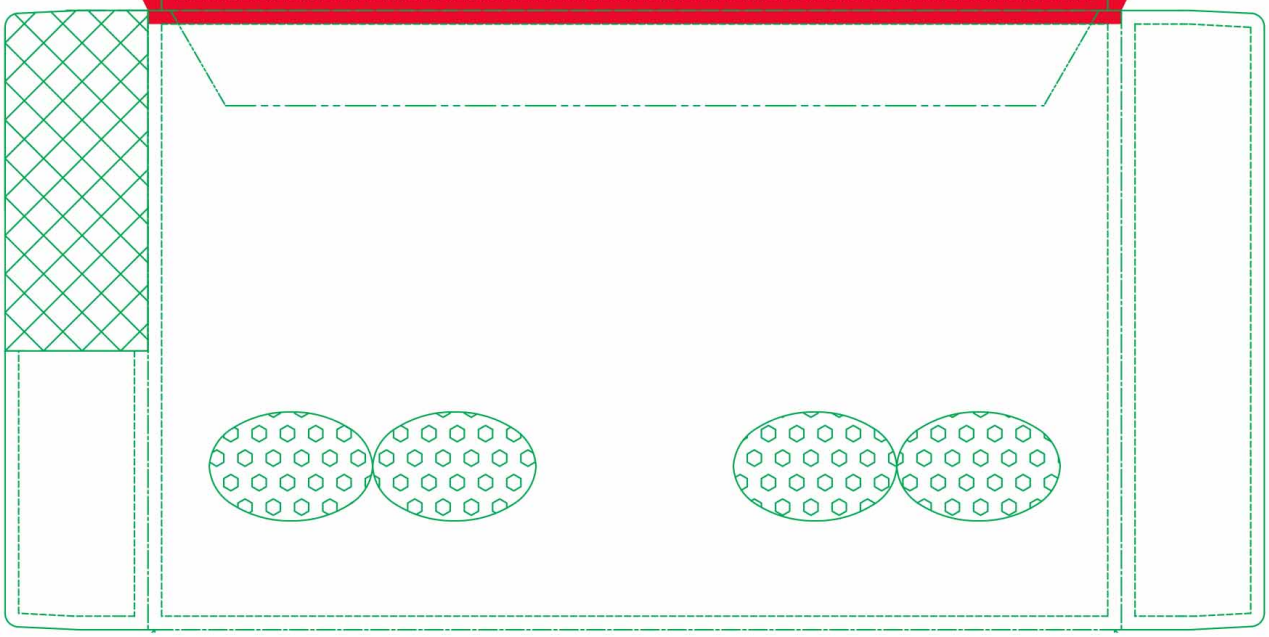
■ liver disease ■ heart disease ■ high blood pressure
■ thyroid disease ■ diabetes
■ trouble urinating due to an enlarged prostate gland
■ persistent or chronic cough such as occurs with smoking, asthma or emphysema
■ cough that occurs with too much phlegm (mucus)

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 ▼



EXTRA STRENGTH TYLENOL COLD PLUS FLU MULTI-ACTION DAY/NIGHT

acetaminophen, pseudoephedrine hydrochloride, dextromethorphan hydrobromide, and chlorpheniramine maleate kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50580-374

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-374-01	1 in 1 PACKAGE	06/21/2021	

Quantity of Parts

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

Part 1 of 2

EXTRA STRENGTH TYLENOL COLD PLUS FLU MULTI-ACTION DAY

acetaminophen, pseudoephedrine hydrochloride, and dextromethorphan hydrobromide tablet, film coated

Product Information

Item Code (Source)	NDC:50580-344
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	30 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	white	**Score**	no score
Shape	OVAL	**Size**	18mm
Flavor		**Imprint Code**	TY;COLD;1408
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	06/21/2021	

Part 2 of 2

EXTRA STRENGTH TYLENOL COLD PLUS FLU MULTI-ACTION NIGHT

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

Product Information	
Item Code (Source)	NDC:50580-286
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 mg
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	30 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg

Inactive Ingredients	
Ingredient Name	**Strength**
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)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	blue	**Score**	no score
Shape	OVAL	**Size**	18mm
Flavor		**Imprint Code**	TY;COLD;1407
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		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	06/21/2021	

Labeler - Johnson & Johnson Consumer Inc. (878046358)

Revised: 1/2024 Johnson & Johnson Consumer Inc.