#### TYLENOL COLD PLUS FLU SEVERE DAY/NIGHT- acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride Kenvue Brands LLC

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#### TYLENOL <sup>®</sup> COLD + FLU SEVERE NIGHT

#### **Drug Facts**

Active ingredients (in each caplet)	Purpose
	Pain
Acetaminophen 325 mg	reliever/fever
	reducer
Chlorpheniramine maleate	Antihistamine
2 mg	
Dextromethorphan HBr	Cough
10 mg	suppressant
Phonylophring UCLE ma	Nasal
Phenylephrine HCl 5 mg	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	<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

- 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 <sup>®</sup> COLD + FLU SEVERE DAY

#### **Drug Facts**

Active ingredients (in each caplet)	Purpose
	Pain
Acetaminophen 325 mg	reliever/fever
	reducer
Dextromethorphan HBr 10	Cough
mg	suppressant
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal
r nenylepinine nei 5 mg	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)

		take 2 caplets every 4 hours
adults and	•	swallow whole; do not crush, chew or

children 12 years and over	<ul><li>dissolve</li><li>do not take more than 10 caplets in 24 hours</li></ul>
children under	

12 years

#### 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<sup>®</sup> 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



renore num to capters at Arnous reen(20:32: "C(BE;71°E(C)) ten did-carnsuce wax, ECG&E true no. 1 alum num microrystaline cellulose, pregeblinited starch, orhate, poweled cellulose, pregeblinited starch mistarchglyco Be, successes, iten ium diox de 17:895-3665 (pul-free) or 115-173-8725 (pul-free)	h professional le fore use. 1 medical leip or contacta Poison Control actor atterationiscritical for adults as well grisor symptoms. Illan directed (see overflose warning) pides every 4 hours whick dond cush, chew or dissolve le more than 10 cushs in 24 hours	LU SEVERS MIGHT	re, pensits form ore than 2 days, is accompanied ear, or vomiting, consult a doctor promptly, appendices priving a doctor or phermacist, admine outcase inhibitor (NWO) (pertaindrugs conditions, or Parkinsorts disease), or for fyour donot know if your prescription drug masist before taking this product. bothis product or any of its ingredients with smoking, asthma or empty sema (mucuis) a or orchion is bo nchitis glaucoma ell you are than ingreases drowsiness or operating machinery
Inactive ingredients canaula wax, crossame bog sodium, Q4C reitw. pd. 10 aluminum bie, Taor, byd cxyp n pyl celluse, hyprome bog, magnesiun sea éte, ni croc ross in inace in the cellubae, polyethytene glycu, i pegetin read start, suce bie, titanium dixote Questions or comments: call+er1995366 halting or 215-275 9755 (collect Tylend* Cold + Flu Severe Day Made in Italy Distributed by: JOHNSON & JOHNSON CONSUMER INC. McNeil Consumer Healthcare Division Fort Washington, PA 19034 USA	Directions     do not take more than directed (see over dose warning)       adults and children     Itake 2 caplets every 4 hours       12 years and over     Iswallow whole; do not crush chew or doscove       idonot take more than 10 caplets in 24 hours     Iswallow whole; do not crush chew or doscove       children under 12 years     Isk a doctor       Other information     Isk a doctor       Beach caplet corrtains: sodium 3 mg     Istore between 20.25°C (68-77°F)       I do not use if bilster unit istom or broken	InviteNote       Coll + FLU SEVERE DAY         Drug Facts (continued)       Inpresent threat-treading, aska health-professional-before use:         If preparater breast-feeding, aska health-professional-before use:       Inpresent threat-feeding, aska health-professional-before use:         Over dose wanning: In case of overd ose, gat m edical help or contact a Poison Control       Center right away; (1-800-222-1222) Quick medical attention is critical for adults as well as brinchida any signs or symptoms.	Drug Facts (continued)         See et the cell warning: If sure threats server, persists for more than 1 days, is accomparied or followed by faver, headache, rash, nausea, or vorniting, consult a doctor promptly.         De not use         with any dhier drug containing acetamin oph en (prescription or nonprescription). If you are not sure which ar a drug on tain so are minion plen, ask a doctor or pharmasis there even had an alergic neaston to this product or any dis ingredients.         Minion of the drug contains acetamin oph en (prescription or nonprescription). If you contains a set in the product or any dis ingredients or enclosed after stopping the MAO() explaines of the doctor or pharmasis before listing this product.         Monitor before use if you have       Inter disease       Inter disease         Bind tabut       Inter disease       Inter disease <tr< td=""></tr<>
Drug	LENOL® COLO + F g Facts ve ingredients (in each caple minophen 325 mg menramine maleate 2 mg.	A Purpose	re using. Keep this box for important information. nore than a total of 10 caplets in a 24-hour period. Take only as directed. TYLENOL® COLD + FLU SEVERE DAY Drug Facts Active ingredients (in each caplet) Pactamophen 325 mg Pain relivent/ever reducer Dextromethorphan HBr 10 mg
Dextro Phenyi Uses m temp temp temp temp tiver this pr may oc writh 3 or Allerg include	lephrine HCl 5 mg	Cough suppressant 	Guidenexis 200 mg

# TYLENOL COLD PLUS FLU SEVERE DAY/NIGHT

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

	oduct Type	HUMAN	OTC DRUG	Item Code	e (Sourc	ce)	NDC:50580	)-414
Pa	ackaging							
#	Item Code	Pac	kage Descr	iption	Mark	ceting Start Date		eting End Date
1	NDC:50580-414- 03	3 in 1 CELLO P	ACK		07/18/2	016		
	NDC:50580-414- 04	1 in 1 CARTON; Package	Type 1: Conve	nience Kit of Co-				
	NDC:50580-414- 04	1 in 1 CARTON			12/21/2	018		
Οι	uantity of Pa	arts						
-	nrt #	Package Q	uantity		Tot	al Product Q	uantity	
Pa	rt 1 2 BLISTER	•	-	8				
Pa	rt 2 2 BLISTER	PACK		16				
<b>T</b> ac		, chlorphenira	amine maleat	<b>VERE NIG</b>		nydrobromide	, and phe	nylephrine
<b>T</b> ac hy	<b>YLENOL C</b> é etaminophen, rdrochloride ta	, chlorphenira blet, film coat	amine maleat			nydrobromide	, and phe	nylephrine
T ac hy Pr	YLENOL Co etaminophen, rdrochloride ta	, chlorphenira blet, film coat <b>mation</b>	amine maleat ced			nydrobromide	, and phe	nylephrine
T ac hy Pr	<b>YLENOL C</b> é etaminophen, rdrochloride ta	, chlorphenira blet, film coat <b>mation</b>	amine maleat			nydrobromide	, and phe	nylephrine
T` ac hy Pr Ro	YLENOL Co etaminophen, rdrochloride ta	, chlorphenira blet, film coat <b>mation</b> istration	orral			nydrobromide	, and phe	nylephrine
T` ac hy Pr Ro	YLENOL Co etaminophen, drochloride ta roduct Infor oute of Admini	, chlorphenira blet, film coat <b>mation</b> istration ient/Active l Ingred	orral Moiety Iient Name	e, dextrometho	rphan h	nydrobromide Basis of S		nylephrine Strengtl
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T`ac hy Pr Ro Ac Ac	YLENOL Co etaminophen, drochloride ta roduct Infor oute of Admini ctive Ingredi ETAMINOPHEN ILORPHENIRAMI	, chlorphenira blet, film coat <b>mation</b> istration ient/Active I Ingred (UNII: 36209ITL NE MALEATE (1	orral orral orral Moiety lient Name 9D) (ACETAMINC UNII: V1Q0090J	e, dextrometho PPHEN - UNII:3620 92) (CHLORPHENIR	rphan ł 9ITL9D)	Basis of S ACETAMINOPHEI CHLORPHENIRAM MALEATE	trength N MINE	Strengt
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POWDERED CELLULOSE (UNII: SMD1X3X09M)	
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

#	ltem 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	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	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** 

								<b>.</b>
			Ingredien			Basis of St	rength	Strength
		-	-	ACETAMINOPHEN - UNII:3620	-	ACETAMINOPHEN		325 mg
			HYDROBROM JNII:7355X3RO	IDE (UNII: 9D2RTI9KYH) FS)		DEXTROMETHORP HYDROBROMIDE	HAN	10 mg
GU	AIFENESIN	(UNII: 495	W7451VQ) (GU	AIFENESIN - UNII:495W7451VQ	2)	GUAIFENESIN		200 mg
	ENYLEPHRI I:1WS297W6		OCHLORIDE (	UNII: 04JA59TNSJ) (PHENYLEPH		PHENYLEPHRINE HYDROCHLORIDE		5 mg
Ina	active In	grediei						
				Ingredient Name			S	Strength
				KE (UNII: CQ3XH3DET6)				
			-	PECIFIED (UNII: 9XZ8H6N6OF	1)			
				: 3NXW29V3WO)				
			E (UNII: 70097M	· ·				
				III: OP1R32D61U)				
				IED (UNII: 3WJQ0SDW1A)				
	CRALOSE (l							
			II: 15FIX9V2JP)					
			R12CBM0EIZ)					
CR	OSCARMEL	LOSE SO	DIUM (UNII: M2	280L1HH48)				
Pr	oduct Ch	naracte	ristics					
Co	lor		yellow	Score		no score		
Sh	ape		OVAL	Size		19mm		
Fla	vor			Imprint Code		TYLENOL;SEVER	RE	
Co	ntains							
Pa	ckaging							
	ltem				Mark	eting Start	Marke	ting End
#	Code		-	Description		Date		ate
1		2 in 1 CA						
1				pe 0: Not a Combination				
		8 in 1 BL		vpe 0: Not a Combination				
1	arketir	8 in 1 BL Product						
1	<b>arketir</b> Marketir Categor	8 in 1 BL Product	ISTER PACK; Ty ormation		Mai	keting Start Date		eting End Date
1 M	Marketir	8 in 1 BL Product	ISTER PACK; Ty ormation	) Number or Monograph	<b>Mai</b> 09/01/	Date		-
1 M	Marketir Categor	8 in 1 BL Product	ISTER PACK; Ty Ormation Application	) Number or Monograph		Date		-
<b>1</b> Ма	Marketir Categor Monograpi	8 in 1 BL Product	ISTER PACK; Ty Ormation Application	Number or Monograph Citation		Date		-
<b>1</b> Ма	Marketir Categor Monograpi	8 in 1 BL Product	Ormation Application 012	Number or Monograph Citation	09/01/	Date	Marke	
1 Ма ото	Marketir Categor Monograph Monograph Marketir Marketir	8 in 1 BL Product	Ormation Application 012	Number or Monograph Citation Number or Monograph	09/01/	Date 2011 keting Start Date	Marke	Date

Revised: 11/2024

Kenvue Brands LLC