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

TYLENOL [®] 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	 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
	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

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- 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

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- skin reddening
- blisters
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If a skin reaction occurs, stop use and seek medical help right away.

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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.

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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	dissolvedo not take more than 10 caplets in 24 hours
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[®] 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



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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				
T ac		, chlorphenira	amine maleat	VERE NIG		nydrobromide	, and phe	nylephrine
T ac hy	YLENOL C 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 mation	amine maleat ced			nydrobromide	, and phe	nylephrine
T ac hy Pr	YLENOL C é etaminophen, rdrochloride ta	, chlorphenira blet, film coat mation	amine maleat			nydrobromide	, and phe	nylephrine
T` ac hy Pr Ro	YLENOL Co etaminophen, rdrochloride ta	, chlorphenira blet, film coat mation 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 mation istration ient/Active l Ingred	orral Moiety Iient Name	e, dextrometho	rphan h	nydrobromide Basis of S		nylephrine Strengtl
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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

								.
			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	arketir 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	Mai 09/01/	Date		-
1 M	Marketir Categor	8 in 1 BL Product	ISTER PACK; Ty Ormation Application) Number or Monograph		Date		-
1 Ма	Marketir Categor Monograpi	8 in 1 BL Product	ISTER PACK; Ty Ormation Application	Number or Monograph Citation		Date		-
1 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