

**TYLENOL COLD PLUS FLU SEVERE DAY AND TYLENOL COLD PLUS FLU PLUS COUGH NIGHT 3-PACK- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, and guaifenesin, phenylephrine hydrochloride
Johnson & Johnson Consumer Inc.**

Tylenol® Cold Plus Flu Severe Day and Tylenol Cold Plus Flu Plus Cough Night 3-Pack

Tylenol® Cold plus Flu plus Cough Night

Drug Facts

Active ingredients (in each 15 mL) Purpose

Acetaminophen 325 mg Pain reliever/ fever reducer

Dextromethorphan HBr 10 mg Cough suppressant

Doxylamine Succinate 6.25 mg Antihistamine

Phenylephrine HCl 5 mg Nasal decongestant

<i>Active ingredients (in each 15 mL)</i>	<i>Purpose</i>
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Doxylamine Succinate 6.25 mg	Antihistamine
Phenylephrine HCl 5 mg	Nasal decongestant

Uses

- temporarily relieves these common cold/flu symptoms:
 - minor aches and pains
 - headache
 - sore throat
 - nasal congestion
 - runny nose and sneezing
 - cough
 - sinus congestion and pressure
- helps clear nasal passages
- relieves cough to help you sleep
- 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
- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- 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
- 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)**
- mL = milliliter
- use only enclosed dosing cup designed for use with this product. Do not use any other dosing device.

adults and children 12 years and over	<ul style="list-style-type: none"> ▪ take 30 mL in the dosing cup provided every 4 hours while symptoms last ▪ do not take more than 150 mL in 24 hours, unless directed by a doctor
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children under 12 years	ask a doctor
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Other information

- each 15 mL contains: **sodium 5 mg**
- store between 20-25°C (68-77°F). Do not refrigerate.
- **do not use if neck band imprinted with "TYLENOL COLD+FLU+COUGH" or foil inner seal imprinted with "SAFETY SEAL®" is broken or missing**

Inactive ingredients

acetic acid, alcohol, anhydrous citric acid, FD&C blue no. 1, FD&C red no. 40, flavors, glycerin, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucralose

Questions or comments?

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

TYLENOL[®] Cold plus Flu Severe

Drug Facts

Active ingredients (in each 30 mL) Purpose

Acetaminophen 650 mg Pain reliever/ fever reducer

Dextromethorphan HBr 20 mg Cough suppressant

Guaifenesin 400 mg Expectorant

Phenylephrine HCl 10 mg Nasal decongestant

Active ingredients (in each 30 mL)	Purpose
Acetaminophen 650 mg	Pain reliever/fever reducer
Dextromethorphan HBr 20 mg	Cough suppressant
Guaifenesin 400 mg	Expectorant
Phenylephrine HCl 10 mg	Nasal decongestant

Uses

- temporarily relieves 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. 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)**
- mL = milliliter
- use only enclosed dosing cup designed for use with this product. Do not use any other dosing device.

adults and children 12 years and over	<ul style="list-style-type: none">▪ take 30 mL in the dosing cup provided every 4 hours while symptoms last▪ do not take more than 150 mL in 24 hours, unless directed by a doctor
children under 12 years	ask a doctor

Other information

- each 30 mL contains: **sodium 10 mg**
- store between 20-25°C (68-77°F).
- **do not use if neck band imprinted with "WARMING SENSATION" or foil inner seal imprinted with "TYLENOL" is broken or missing**

Inactive ingredients

anhydrous citric acid, FD&C blue no. 1, FD&C red no. 40, FD&C yellow no. 6, flavors, glycerin, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucralose

Questions or comments?

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

PRINCIPAL DISPLAY PANEL

NDC 50580-529-01

DAYTIME

DAYTIME

NIGHTTIME



PRINCIPAL DISPLAY PANEL

30040371
NDC 50580-369-01

TYLENOL[®]
FOR ADULTS
COLD + FLU + COUGH

Acetaminophen, Dextromethorphan HBr, Doxylamine Succinate, Phenylephrine HCl,
Pain Reliever-Fever Reducer, Cough Suppressant, Antihistamine, Nasal Decongestant

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

NIGHT

WILD BERRY
BURST

Alcohol 0.7%
8 fl oz (240 mL)

30040371

NDC 50580-369-01

TYLENOL[®]

FOR ADULTS

COLD + FLU + COUGH**Acetaminophen**, Dextromethorphan HBr, Doxylamine Succinate, Phenylephrine HCl,
Pain Reliever-Fever Reducer, Cough Suppressant, Antihistamine, Nasal Decongestant

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



NIGHT

WILD BERRY
BURST

Alcohol 0.7%

8 fl oz (240 mL)

OPEN TO READ DRUG FACTS
(Warnings, Directions...)

PEEL

30040372

Do not use if neck band imprinted with
"TYLENOL COLD+FLU+ COUGH" or foil
inner seal imprinted with "SAFETY
SEAL" is broken or missing.**DO NOT USE WITH OTHER MEDICINES
CONTAINING ACETAMINOPHEN**

3 0045-0562-08 1

Drug Facts**Active ingredients Purpose
(in each 15 mL)**Acetaminophen 325 mg Pain reliever/
fever reducerDextromethorphan HBr 10 mg.....Cough suppressant
Doxylamine Succinate 6.25 mg.....Antihistamine
Phenylephrine HCl 5 mg.....Nasal decongestant**Uses**

- temporarily relieves these common cold/flu symptoms:
 - minor aches and pains
 - headache
 - nasal congestion
 - runny nose and sneezing
 - cough
 - sinus congestion and pressure
 - helps clear nasal passages
- sore throat

Drug Facts (continued)

- relieves cough to help you sleep
- 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

Drug Facts (continued)

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

Drug Facts (continued)

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
- a breathing problem such as

Drug Facts (continued)

- emphysema or chronic bronchitis
- glaucoma
- 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
- taking sedatives or tranquilizers

When using this product

- do not exceed recommended dose
- excitability may occur, especially in children
- marked drowsiness may occur

Drug Facts (continued)

- 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.

Drug Facts (continued)

If pregnant or breast-feeding, ask a health professional before use.

Drug Facts (continued)

adults take 30 mL in the dosing cup provided every 4

Drug Facts (continued)

is broken or missing

TYLENOL[®]
COLD + FLU + COUGH
NIGHT

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)
- mL = milliliter
- use only enclosed dosing cup designed for use with this product. Do not use any other dosing device.

and children 12 years and over	cup provided every 4 hours while symptoms last ■ do not take more than 150 mL in 24 hours, unless directed by a doctor
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children under 12 years	ask a doctor
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Other information

- each 15 mL contains: sodium 5 mg
- store between 20-25°C (68-77°F). Do not refrigerate.
- do not use if neck band imprinted with "TYLENOL COLD+FLU+COUGH" or foil inner seal imprinted with "SAFETY SEAL®"

Inactive ingredients
acetic acid, alcohol, anhydrous citric acid, FD&C blue no. 1, FD&C red no. 40, flavors, glycerin, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucralose

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

PARENTS:

Learn about teen medicine abuse

www.StopMedicineAbuse.org

How can we help?

1-877-895-3665

SNAP THIS CODE OR TEXT TYCOLD7 TO 87715

MSG & DATA RATES MAY APPLY. TEXT HELP FOR HELP. TEXT STOP FOR STOP.



Acetaminophen (325 mg per 15 mL)
Dextromethorphan HBr (10 mg per 15 mL)
Doxylamine succinate (6.25 mg per 15 mL)
Phenylephrine HCl (5 mg per 15 mL)

8 fl oz (240 mL)

Distributed by:
JOHNSON & JOHNSON CONSUMER INC.
McNeil Consumer Healthcare Division
Fort Washington, PA 19034 USA
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30040372

PRINCIPAL DISPLAY PANEL

NDC 50580-403-08

30049843

Warming Honey Lemon Flavor

TYLENOL®

FOR ADULTS

COLD + FLU SEVERE

Acetaminophen, Dextromethorphan HBr, Phenylephrine HCl, Guaifenesin

Pain Reliever-Fever Reducer, Cough Suppressant, Nasal Decongestant, Expectorant

Alcohol Free

DAY

NON-DROWSY

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

8 fl oz (240 mL)



COLD + FLU SEVERE

Acetaminophen

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

Alcohol Free

 **DAY
NON-DROWSY**

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



8 fl oz (240 mL)



OPEN TO READ DRUG FACTS → **PEEL**
(Warnings, Directions...)

EXP./LOT:

30049845 Do not use if neck band imprinted with
"WARMING SENSATION" or foil
inner seal imprinted with "TYLENOL"
is broken or missing.

**DO NOT USE WITH OTHER MEDICINES
CONTAINING ACETAMINOPHEN**



Drug Facts

Active ingredients Purpose
(in each 30 mL)

- Acetaminophen 650 mg.....Pain reliever/
fever reducer
- Dextromethorphan HBr 20 mg.....Cough suppressant
- Guaifenesin 400 mg.....Expectorant
- Phenylephrine HCl 10 mg.....Nasal decongestant

Uses

- temporarily relieves the following cold/flu

Drug Facts (continued)

- 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

PAGE 2

PAGE 3

symptoms:

- minor aches and pains
- headache
- nasal congestion
- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive
- sore throat
- cough

- 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

Drug Facts (continued)

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,

Drug Facts (continued)

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

Drug Facts (continued)

- 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

Drug Facts (continued)

- 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.

Drug Facts (continued)

Drug Facts (continued)

Directions

- do not take more than directed (see overdose warning)
- mL = milliliter
- use only enclosed dosing cup designed for use with this product. Do not use any other dosing device.

adults and children 12 years and over	■ take 30 mL in the dosing cup provided every 4 hours while symptoms last
children under 12 years	■ do not take more than 150 mL in 24 hours, unless directed by a doctor

children under 12 years	ask a doctor
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Other information

- each 30 mL contains: sodium 10 mg
- store between 20-25°C (68-77°F).
- do not use if neck band imprinted with "WARMING SENSATION" or foil inner seal imprinted with "TYLENOL" is broken or missing

Inactive ingredients

anhydrous citric acid, FD&C blue no. 1, FD&C red no. 40, FD&C yellow no. 6, flavors, glycerin, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucralose

Drug Facts (continued)

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

PARENTS:

Learn about teen medicine abuse

www.StopMedicineAbuse.org

TYLENOL®
COLD + FLU SEVERE

How can we help?
☎ 1-877-895-3665

Acetaminophen (650 mg per 30 mL)
Dextromethorphan HBr (20 mg per 30 mL)
Guaifenesin (400 mg per 30 mL)
Phenylephrine HCl (10 mg per 30 mL)

8 fl oz (240 mL)

Distributed by:
JOHNSON & JOHNSON CONSUMER INC.
McNeil Consumer Healthcare Division
Fort Washington, PA 19034 USA
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30049845

TYLENOL COLD PLUS FLU SEVERE DAY AND TYLENOL COLD PLUS FLU PLUS COUGH NIGHT 3-PACK

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, and guaifenesin, phenylephrine hydrochloride kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50580-529
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-529-01	1 in 1 PACKAGE	08/05/2019	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	240 mL
Part 2	2 BOTTLE, PLASTIC	480 mL

Part 1 of 2

TYLENOL COLD PLUS FLU PLUS COUGH NIGHT

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, and phenylephrine hydrochloride solution

Product Information

Item Code (Source) NDC:50580-369

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg in 15 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 15 mL
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg in 15 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 15 mL

Inactive Ingredients

Ingredient Name	Strength
ACETIC ACID (UNII: Q40Q9N063P)	
ALCOHOL (UNII: 3K9958V90M)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	

SUCRALOSE (UNII: 96K6UQ3ZD4)

Product Characteristics

Color	purple	Score	
Shape		Size	
Flavor	BERRY (Berry Mint)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-369-01	240 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	06/17/2019	

Part 2 of 2

TYLENOL COLD PLUS FLU SEVERE

acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride solution

Product Information

Item Code (Source)	NDC:50580-403
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 30 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 30 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 30 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	brown, yellow (Amber colored)	Score	
Shape		Size	
Flavor	HONEY, LEMON (honey lemon flavored)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-403-08	240 mL in 1 BOTTLE, PLASTIC; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	07/05/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	08/05/2019	

Labeler - Johnson & Johnson Consumer Inc. (878046358)

Revised: 1/2024

Johnson & Johnson Consumer Inc.