TYLENOL SINUS SEVERE- acetaminophen, guaifenesin, phenylephrine hydrochloride tablet
Lil' Drug Store Products, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

TYLENOL ®
SINUS
SEVERE

Drug Facts

Drug Facts

Active Ingredient (in each tablet)

Purpose

Active ingredients (in each caplet)	***Purpose***
Acetaminophen 325 mg	Pain reliever/fever reducer
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

Uses

- temporarily relieves these symptoms associated with hay fever or other respiratory allergies, and the common cold:

sinus congestion and pressure

- headache
- nasal congestion
- minor aches and pains

- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive
- temporarily reduces fever

Warnings

Liver warning

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

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.

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 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

- each caplet contains: sodium 3 mg
- store between 20-25°C (68-77°F)
- do not use if pouch is torn or damaged

INACTIVE INGREDIENTS

carnauba wax, croscarmellose sodium, flavor, hydroxypropyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, pregelatinized starch, sucralose, titanium dioxide, triacetin

QUESTIONS OR COMMENTS?

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

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

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McNeil Consumer Healthcare Division, Fort Washington, PA 19034 USA

Repackaged and distributed by: Convenience Valet ®, Glendale Heights, IL 60139

PRINCIPAL DISPLAY PANEL

TYLENOL ®
FOR ADULTS

SINUS SEVERE

Acetaminophen, Phenylephrine HCl, Guaifenesin
Pain Reliever–Fever Reducer, Nasal Decongestant, Expectorant

SINUS HEADACHE
SINUS PRESSURE
NASAL CONGESTION
MUCUS + CHEST CONGESTION

DAY
NON-DROWSY

2 POUCHES OF 2 CAPLETS EACH

PRINCIPAL DISPLAY PANEL 25ct Box

TYLENOL ®
FOR ADULTS

SINUS SEVERE

Acetaminophen, Phenylephrine HCl, Guaifenesin
Pain Reliever–Fever Reducer, Nasal Decongestant, Expectorant

SINUS HEADACHE

SINUS PRESSURE
NASAL CONGESTION
MUCUS + CHEST CONGESTION

DAY
NON-DROWSY

25 POUCHES OF 2 CAPLETS EACH

PRINCIPAL DISPLAY PANEL 30ct Box

TYLENOL ®
FOR ADULTS

SINUS SEVERE

Acetaminophen, Phenylephrine HCl, Guaifenesin
Pain Reliever–Fever Reducer, Nasal Decongestant, Expectorant

SINUS HEADACHE
SINUS PRESSURE
NASAL CONGESTION
MUCUS + CHEST CONGESTION

DAY
NON-DROWSY

30 POUCHES OF 2 CAPLETS EACH

CVP 4 Count Carton

TYLENOL ®
FOR ADULTS

COLD + FLU
SEVERE

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

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

4

Caplet

2 Pouches of 2 Caplets each

CVP

HEALTH

TYLENOL SINUS SEVERE

acetaminophen, guaifenesin, phenylephrine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:29485-6557

Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	

Product Characteristics

Color	white	**Score**	no score
Shape	OVAL	**Size**	20mm
Flavor	MINT	**Imprint Code**	TYLENOL;1072
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:29485-6557-4	2 in 1 CARTON	08/25/2017	
1		2 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M012	08/25/2017	

TYLENOL SINUS SEVERE

acetaminophen, guaifenesin, phenylephrine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:29485-8055
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	

Product Characteristics

Color	white	**Score**	no score
Shape	OVAL	**Size**	20mm
Flavor	MINT	**Imprint Code**	TYLENOL;1072
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:29485-8055-4	2 in 1 BLISTER PACK	04/18/2017	05/06/2025
1		2 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	04/18/2017	05/06/2025

TYLENOL SINUS SEVERE

acetaminophen, guaifenesin, phenylephrine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:29485-8057
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics

Color	white	**Score**	no score
Shape	OVAL	**Size**	20mm
Flavor	MINT	**Imprint Code**	TYLENOL;1072
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:29485-8057-2	25 in 1 BOX	07/20/2020	
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:29485-8057-3	30 in 1 BOX	08/22/2017	
2		2 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M012	08/22/2017	

Labeler - Lil' Drug Store Products, Inc. (093103646)

Revised: 7/2023 Lil' Drug Store Products, Inc.