TYLENOL SINUS PLUS HEADACHE DAY- acetaminophen and phenylephrine hydrochloride tablet, film coated
Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division

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 + HEADACHE DAY

Drug Facts

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

Uses

- temporarily relieves these symptoms associated with hay fever or other respiratory allergies, and the common cold:
  - headache
  - sinus congestion and pressure
  - nasal congestion
  - minor aches and pains
- helps decongest sinus openings and passages
- promotes sinus drainage
- helps clear nasal passages
- 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.

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

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 or nasal congestion 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

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, D&C yellow no. 10 aluminum lake, FD&C blue no. 1 aluminum

lake, FD&C red no. 40 aluminum lake, flavors, hypromellose, magnesium stearate, microcrystalline cellulose, modified starch, polyethylene glycol, polysorbate 80, potassium sorbate, powdered cellulose, pregelatinized starch, sodium benzoate, sodium citrate, sodium starch glycolate, sucralose, titanium dioxide

Questions or comments?

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

PRINCIPAL DISPLAY PANEL

NDC 50580-598-02

TYLENOL®
FOR ADULTS

SINUS
+ HEADACHE

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

DAY
NON-DROWSY

- SINUS HEADACHE
- SINUS PRESSURE
- NASAL CONGESTION

Actual Size

24 CAPLETS

TYLENOL SINUS PLUS HEADACHE DAY

acetaminophen and phenylephrine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50580-598
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Acetaminophen (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)	Acetaminophen	325 mg
Phenylephrine hydrochloride (UNII: 04JA59TNSJ) (Phenylephrine - UNII:1WS297W6MV)	Phenylephrine hydrochloride	5 mg

Inactive Ingredients

Ingredient Name	Strength
anhydrous citric acid (UNII: XF417D3PSL)	
carnauba wax (UNII: R12CBM0EIZ)	

D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
FD&C red no. 40 (UNII: WZB9127XOA)	
aluminum oxide (UNII: LMI26O6933)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
magnesium stearate (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
polysorbate 80 (UNII: 6OZP39ZG8H)	
potassium sorbate (UNII: 1VPU26JZZ4)	
powdered cellulose (UNII: SMD1X3XO9M)	
sodium benzoate (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
sodium starch glycolate type a potato (UNII: 5856J3G2A2)	
sucralose (UNII: 96K6UQ3ZD4)	
titanium dioxide (UNII: 15FIX9V2JP)	

Product Characteristics

Color	GREEN	**Score**	no score
Shape	OVAL	**Size**	18mm
Flavor	MINT	**Imprint Code**	TYLENOL;1080
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-598-01	2 in 1 CARTON	07/15/2015	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:50580-598-02	2 in 1 CARTON	05/08/2019	
2		12 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 FINAL	part341	07/15/2015	

Labeler - Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division (878046358)

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