TYLENOL EXTRA STRENGTH- acetaminophen tablet, 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® Extra Strength

Drug Facts

Active ingredient (in each caplet)

Acetaminophen 500 mg

Purpose

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
 - the common cold
 - headache
 - backache
 - minor pain of arthritis
 - toothache
 - muscular aches
 - premenstrual and menstrual cramps
- 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

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 allergic to acetaminophen or any of the inactive ingredients in this product

Ask a doctor before use if you have liver disease

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin

Stop use and ask a doctor if

- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- new symptoms occur

redness or swelling is present

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 6 hours while symptoms last do not take more than 6 caplets in 24 hours, unless directed by a doctor do not use for more than 10 days unless directed by a doctor
children under 12 years	ask a doctor

Other information

- store between 20-25°C (68-77°F)
- do not use if carton is opened or neck wrap or foil inner seal imprinted with "SAFETY SEAL®" is broken or missing

Inactive ingredients

carnauba wax^1 , castor oil¹, corn starch, FD&C red no. 40 aluminum lake, hypromellose, magnesium stearate, polyethylene glycol¹, powdered cellulose, pregelatinized starch, propylene glycol, shellac, sodium starch glycolate, titanium dioxide

Questions or comments?

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

PRINCIPAL DISPLAY PANEL

NDC 50580-451-50

See New Warnings Information & Directions

TYLENOL®

Pain Reliever Fever Reducer

¹ contains one or more of these ingredients

Acetaminophen

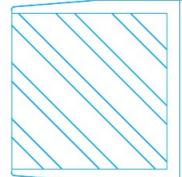
EXTRA STRENGTH For Adults

50 CAPLETS 500 mg each

Caplets

For Hospital and Government Use Only





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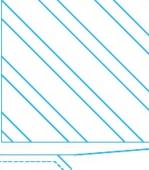
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See New Warnings Information & Directions Acetaminophen STI 50 CAPLETS 500 mg each Caplets

For Hospital and Government Use Only

50 Caplets

30021097/150018994-03

For Hospital and Government Use Only Distributed by: McNeil Consumer Healthcare Division of McNEIL-PPC, Inc. Fort Washington, PA 19034 USA 6McNEIL-PPC, INC. 2012 Visit us at www.lylandl.com or call 1-877-TYLENOL (1-877-895-3665)

Contains No Aspirin



Drug Facts (continued)

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TYLENOL EXTRA STRENGTH

acetaminophen tablet, coated

Product	Inform	nation
Product	HIDHII	ıauvıı

Product Type HUMAN OTC DRUG Item Code (Source) NDC:50580-451

Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Acetaminophen (UNII: 36209 ITL9D) (Acetaminophen - UNII: 36209 ITL9D)	Acetaminophen	500 mg	

Inactive Ingredients		
Ingredient Name	Strength	
Carnauba wax (UNII: R12CBM0EIZ)		
castor oil (UNII: D5340 Y219 G)		
starch, corn (UNII: O8232NY3SJ)		
FD&C red No. 40 (UNII: WZB9127XOA)		
aluminum oxide (UNII: LMI26O6933)		
hypromellose, unspecified (UNII: 3NXW29V3WO)		
magnesium stearate (UNII: 70097M6I30)		
Polyethylene glycol, unspecified (UNII: 3WJQ0SDW1A)		
powdered cellulose (UNII: SMD1X3XO9M)		
propylene glycol (UNII: 6DC9Q167V3)		
shellac (UNII: 46N107B71O)		
Sodium Starch Glycolate Type A Potato (UNII: 5856J3G2A2)		
titanium dioxide (UNII: 15FIX9V2JP)		

Product Characteristics			
Color	WHITE	Score	no score
Shape	OVAL	Size	18 mm
Flavor		Imprint Code	TYLENOL;500;HOSPITAL
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:50580-451- 03	150 in 1 CARTON	08/19/1994	11/30/2016
1	1 in 1 POUCH; Type 0: Not a Combination Product		
2 NDC:50580-451- 10	10 in 1 CARTON	06/30/2014	0 1/3 1/2 0 19
2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3 NDC:50580-451- 50	1 in 1 CARTON	08/19/1994	
3	50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
4 NDC:50580-451-70	700 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/19/1994	

Marketing Informat	tion		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

08/19/1994

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

Revised: 3/2019

Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division