TYLENOL EXTRA STRENGTH- acetaminophen 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.

Extra Strength TYLENOL

Drug Facts

Active ingredient (in each tablet)

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

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 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 tablets every 6 hours while symptoms last ■ do not take more than 6 tablets 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 neck band or foil inner seal imprinted with "TYLENOL" is broken or missing**

Inactive ingredients

carnauba wax, FD&C red no. 40 aluminum lake, FD&C yellow no. 6 aluminum lake, hypromellose, iron oxide, magnesium stearate, modified starch[1], polyethylene glycol, polysorbate 80, powdered cellulose, pregelatinized starch, purified water, sodium starch glycolate, sucralose, titanium dioxide

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[1] may contain

Questions or comments?

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

PRINCIPAL DISPLAY PANEL

NDC 50580-590-02

Extra Strength
TYLENOL®
FOR ADULTS

Acetaminophen

Pain Reliever
Fever Reducer

COATED
TABLETS

Actual Size

100 Tablets
500 mg each

TYLENOL EXTRA STRENGTH

acetaminophen tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50580-590
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
acetaminophen (UNII: 362O9ITL9D) (acetaminophen - UNII:362O9ITL9D)	acetaminophen	500 mg

Inactive Ingredients

Ingredient Name	Strength
carnauba wax (UNII: R12CBM0EIZ)	
FD&C red no. 40 (UNII: WZB9127XOA)	
FD&C yellow no. 6 (UNII: H77VEI93A8)	
aluminum oxide (UNII: LMI26O6933)	
hypromellose, unspecified (UNII: 3NXW29V3WO)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
magnesium stearate (UNII: 70097M6I30)	
polyethylene glycol, unspecified (UNII: 3WJQ0SDW1A)	
polysorbate 80 (UNII: 6OZP39ZG8H)	
powdered cellulose (UNII: SMD1X3XO9M)	
water (UNII: 059QF0KO0R)	
sodium starch glycolate type a potato (UNII: 5856J3G2A2)	
sucralose (UNII: 96K6UQ3ZD4)	
titanium dioxide (UNII: 15FIX9V2JP)	

Product Characteristics

Color	RED	**Score**	no score
Shape	ROUND	**Size**	12mm
Flavor		**Imprint Code**	TYLENOL;500
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-590-01	1 in 1 CARTON	07/16/2018	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:50580-590-02	1 in 1 CARTON	07/16/2018	
2		100 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:50580-590-03	1 in 1 CARTON	07/16/2018	
3		225 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:50580-590-04	1 in 1 CARTON	07/31/2020	
4		24 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:50580-590-05	1 in 1 CARTON	07/31/2020	
5		100 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:50580-590-06	1 in 1 CARTON	07/31/2020	
6		225 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	07/16/2018	

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

Revised: 5/2020 Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division