TYLENOL EXTRA STRENGTH- acetaminophen tablet, film coated
Johnson & Johnson Consumer Inc.

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: 3WQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
WATER (UNII: 059QF0KO0R)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
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	04/30/2020
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:50580-590-02	1 in 1 CARTON	07/16/2018	02/28/2021
2		100 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:50580-590-03	1 in 1 CARTON	07/16/2018	04/30/2020
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 Drug	M013	07/16/2018	

Labeler - Johnson & Johnson Consumer Inc. (878046358)

Revised: 1/2024 Johnson & Johnson Consumer Inc.