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.

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

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 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. Do not use if foil inner seal imprinted with "TYLENOL" is broken or missing**

Inactive ingredients

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

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[1] contains one or more of these ingredients

Questions or comments?

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

PRINCIPAL DISPLAY PANEL

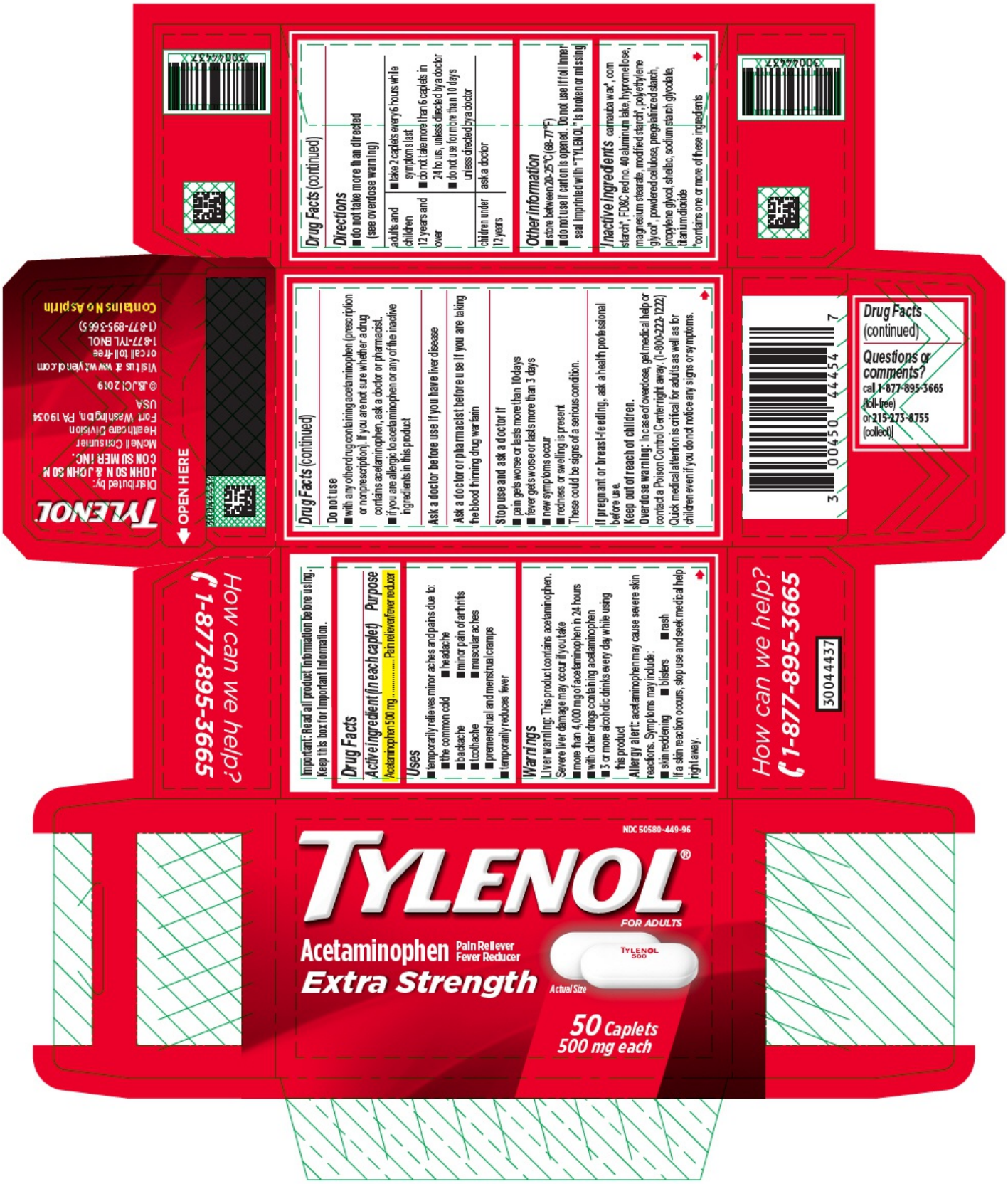
NDC 50580-449-96

TYLENOL®
FOR ADULTS

Acetaminophen
Pain Reliever
Fever Reducer

Extra Strength
Actual Size

50 Caplets
500 mg each



TYLENOL EXTRA STRENGTH

acetaminophen tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50580-449

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)	
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**	19mm
Flavor		**Imprint Code**	TYLENOL;500
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-449-00	1 in 1 CARTON	08/19/1984	
1		125 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:50580-449-05	1 in 1 CARTON	08/19/1984	
2		24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:50580-449-08	2 in 1 POUCH; Type 0: Not a Combination Product	08/19/1984	
4	NDC:50580-449-09	1 in 1 CARTON	08/19/1984	
4		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
5	NDC:50580-449-10	50 in 1 TRAY	08/19/1984	
5	NDC:50580-449-08	2 in 1 POUCH; Type 0: Not a Combination Product		
6	NDC:50580-449-11	50 in 1 TRAY	08/19/1984	

6	NDC:50580-449-08	2 in 1 POUCH; Type 0: Not a Combination Product		
7	NDC:50580-449-13	3 in 1 CARTON	08/19/1984	
7	NDC:50580-449-08	2 in 1 POUCH; Type 0: Not a Combination Product		
8	NDC:50580-449-14	2 in 1 POUCH; Type 0: Not a Combination Product	08/19/1984	
9	NDC:50580-449-15	10 in 1 VIAL, PLASTIC; Type 0: Not a Combination Product	08/19/1984	
10	NDC:50580-449-23	1 in 1 CARTON	08/19/1984	
10		150 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
11	NDC:50580-449-31	1 in 1 CARTON	08/19/1984	
11		36 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
12	NDC:50580-449-34	325 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/19/1984	
13	NDC:50580-449-35	1 in 1 CARTON	08/19/1984	
13		24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
14	NDC:50580-449-36	1 in 1 CARTON	08/19/1984	
14		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
15	NDC:50580-449-61	1 in 1 CARTON	08/19/1984	
15		225 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
16	NDC:50580-449-62	325 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/19/1984	
17	NDC:50580-449-84	2 in 1 POUCH; Type 0: Not a Combination Product	08/19/1984	
18	NDC:50580-449-85	50 in 1 TRAY	08/19/1984	
18	NDC:50580-449-84	2 in 1 POUCH; Type 0: Not a Combination Product		
19	NDC:50580-449-86	50 in 1 TRAY	08/19/1984	
19	NDC:50580-449-84	2 in 1 POUCH; Type 0: Not a Combination Product		
20	NDC:50580-449-87	3 in 1 CARTON	08/19/1984	
20	NDC:50580-449-84	2 in 1 POUCH; Type 0: Not a Combination Product		
21	NDC:50580-449-12	12 in 1 PACKAGE	10/21/2014	
21		10 in 1 VIAL, PLASTIC; Type 0: Not a Combination Product		
22	NDC:50580-449-96	1 in 1 CARTON	06/25/2018	
22		50 in 1 BOTTLE; Type 0: Not a Combination Product		
23	NDC:50580-449-97	249 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	01/28/2019	
24	NDC:50580-449-98	110 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	01/28/2019	

Marketing Information

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

OTC MONOGRAPH NOT FINAL	part343	08/19/1984	

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

Revised: 7/2019 Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division