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 gelcap)

Acetaminophen 500 mg

Purpose

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
  - headache
  - muscular aches
  - backache
  - minor pain of arthritis
  - the common cold
  - toothache
  - 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 gelcaps every 6 hours while symptoms last ■ do not take more than 6 gelcaps 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). Avoid high humidity.
- **do not use if carton is opened. Do not use if foil inner seal imprinted with "TYLENOL" is broken or missing**

Inactive ingredients

benzyl alcohol, butylparaben, carboxymethylcellulose sodium, D&C yellow no. 10, edetate calcium disodium, FD&C blue no. 1, FD&C red no. 40, gelatin, hypromellose, iron oxide, magnesium stearate, methylparaben, modified starch, polyethylene glycol, polysorbate 80, powdered cellulose, pregelatinized starch, propylene glycol, propylparaben, red iron oxide, sodium lauryl sulfate, sodium propionate, sodium starch glycolate, titanium dioxide, yellow iron oxide

Questions or comments?

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

PRINCIPAL DISPLAY PANEL

NDC 50580-488-24

Extra Strength
TYLENOL®
FOR ADULTS

Acetaminophen
Pain Reliever
Fever Reducer

RAPID RELEASE
GELS

Actual Size

24 Gelcaps*
500 mg each

*Gelatin-Coated Tablets

TYLENOL EXTRA STRENGTH

acetaminophen tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50580-488
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
benzyl alcohol (UNII: LKG8494WBH)	
butylparaben (UNII: 3QPI1U3FV8)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
D&C yellow no. 10 (UNII: 35SW5USQ3G)	
edetate calcium disodium (UNII: 25IH6R4SGF)	
FD&C blue no. 1 (UNII: H3R47K3TBD)	
FD&C red no. 40 (UNII: WZB9127XOA)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
magnesium stearate (UNII: 70097M6I30)	
methylparaben (UNII: A2I8C7HI9T)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
polysorbate 80 (UNII: 6OZP39ZG8H)	
powdered cellulose (UNII: SMD1X3XO9M)	
propylene glycol (UNII: 6DC9Q167V3)	
propylparaben (UNII: Z8IX2SC1OH)	
ferric oxide red (UNII: 1K09F3G675)	
sodium lauryl sulfate (UNII: 368GB5141J)	
sodium propionate hydrate (UNII: DK6Y9P42IN)	
sodium starch glycolate type A potato (UNII: 5856J3G2A2)	
titanium dioxide (UNII: 15FIX9V2JP)	
ferric oxide yellow (UNII: EX438O2MRT)	

Product Characteristics

Color	RED, BLUE, GRAY	**Score**	no score
Shape	OVAL	**Size**	21mm
Flavor		**Imprint Code**	TY;500
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-488-10	1 in 1 CARTON	01/16/2017	
1		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:50580-488-24	1 in 1 CARTON	01/16/2017	
2		24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

3	NDC:50580-488-25	1 in 1 CARTON	01/16/2017	
3		225 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
4	NDC:50580-488-28	290 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/16/2017	
5	NDC:50580-488-01	50 in 1 TRAY	04/17/2017	12/31/2018
5		2 in 1 POUCH; Type 0: Not a Combination Product		
6	NDC:50580-488-52	1 in 1 CARTON	06/17/2019	
6		50 in 1 BOTTLE, PLASTIC; 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	01/16/2017	

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

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