

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

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	<ul style="list-style-type: none">▪ 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, crospovidone, FD&C red no. 40 aluminum lake, hypromellose,

magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, propylene glycol, shellac glaze, sodium starch glycolate, stearic acid, titanium dioxide

Questions or comments?

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

PRINCIPAL DISPLAY PANEL

NDC 50580-378-06

TYLENOL[®]
FOR ADULTS

Acetaminophen
Pain Reliever
Fever Reducer

Extra Strength

Actual Size

100 Caplets
500 mg each

Drug Facts

Active ingredient (in each caplet)

Purpose

Acetaminophen 500 mg Pain reliever/fever reducer

Uses

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

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 redness
- hives
- 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

Drug Facts (continued)

- 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 breastfeeding, 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 | take 2 caplets every 6 hours while symptoms last and children |
| 12 years and over | do not take more than 6 caplets in 24 hours, unless directed by a doctor |
| children under 12 years | do not use for more than 10 days unless directed by a doctor |
- 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

canthaxanthin, croscopolone, FD&C red no. 40 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polydiallyl methacrylate, polyethylene glycol, polyvinylpyrrolidone, povidone, pregelatinized starch, polyethylene glycol, shellac, glaze, sodium starch glycolate, stearic acid, titanium dioxide

Questions or comments?

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



How can we help?
1-877-895-3665

TYLENOL[®]

FOR ADULTS

Acetaminophen Pain Reliever
Fever Reducer

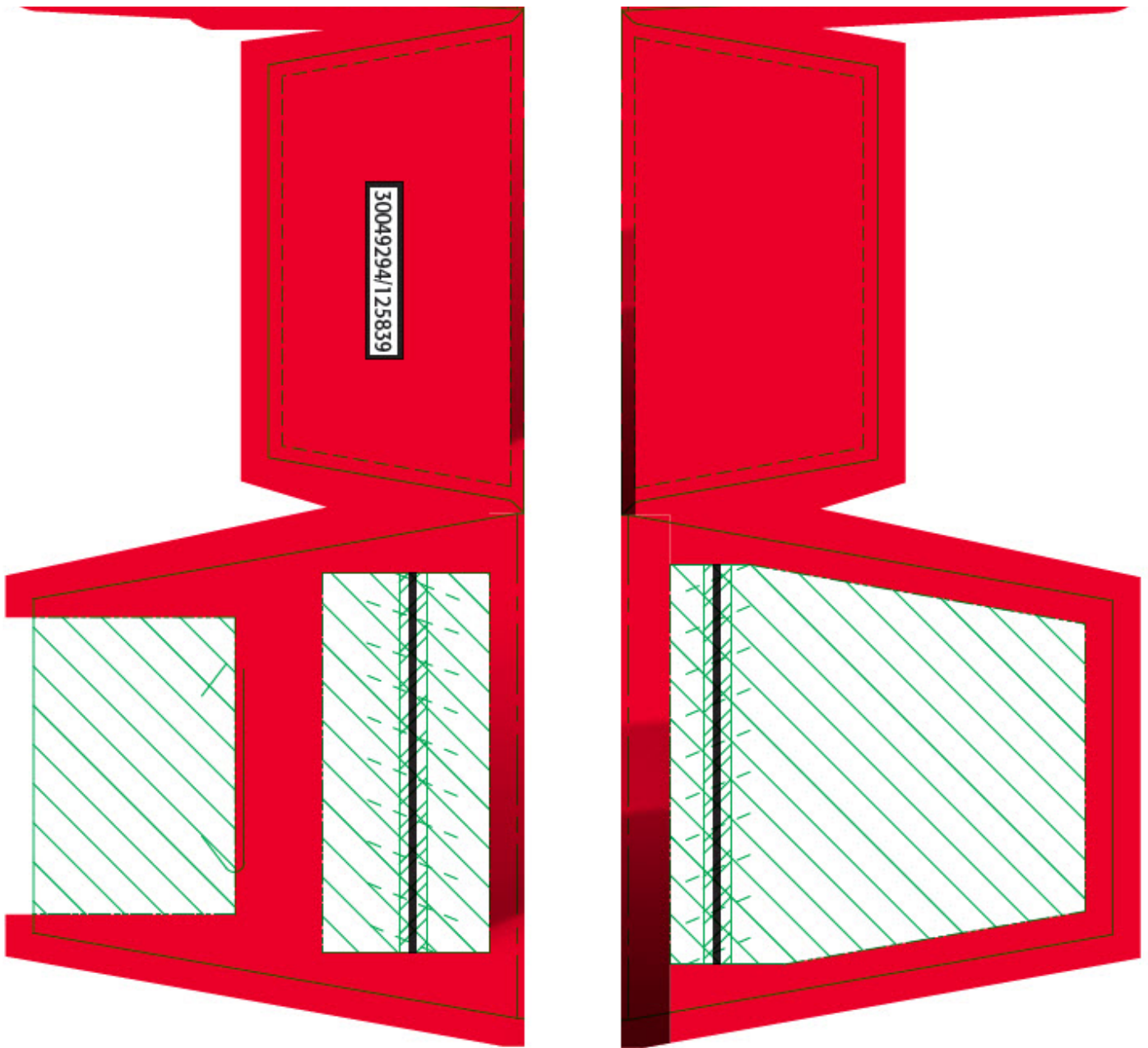
Extra Strength



Actual Size

100 Caplets
500 mg each





TYLENOL EXTRA STRENGTH

acetaminophen tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50580-378
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
ALUMINUM OXIDE (UNII: LMI26O6933)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CROSPVIDONE (UNII: 2S7830E561)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
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:50580-378-01	1 in 1 CARTON	11/01/2014	
1		24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:50580-378-02	1 in 1 CARTON	11/01/2014	
2		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:50580-378-03	225 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/06/2015	
4	NDC:50580-378-04	1 in 1 CARTON	03/01/2021	
4		24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
5	NDC:50580-378-05	1 in 1 CARTON	03/01/2021	
5		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
6	NDC:50580-378-06	1 in 1 CARTON	03/01/2021	
6		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
7	NDC:50580-378-07	1 in 1 CARTON	03/01/2021	
7		225 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

8	NDC:50580-378-08	325 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/01/2021	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013		11/01/2014	

Labeler - Johnson & Johnson Consumer Inc. (878046358)

Revised: 1/2024

Johnson & Johnson Consumer Inc.