TYLENOL EXTRA STRENGTH- acetaminophen tablet, film coated
Navajo Manufacturing Company 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 if 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 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)
- see bottom of dispensit for lot number and expiration date
- do not use if pouch is torn or damaged

Inactive ingredients

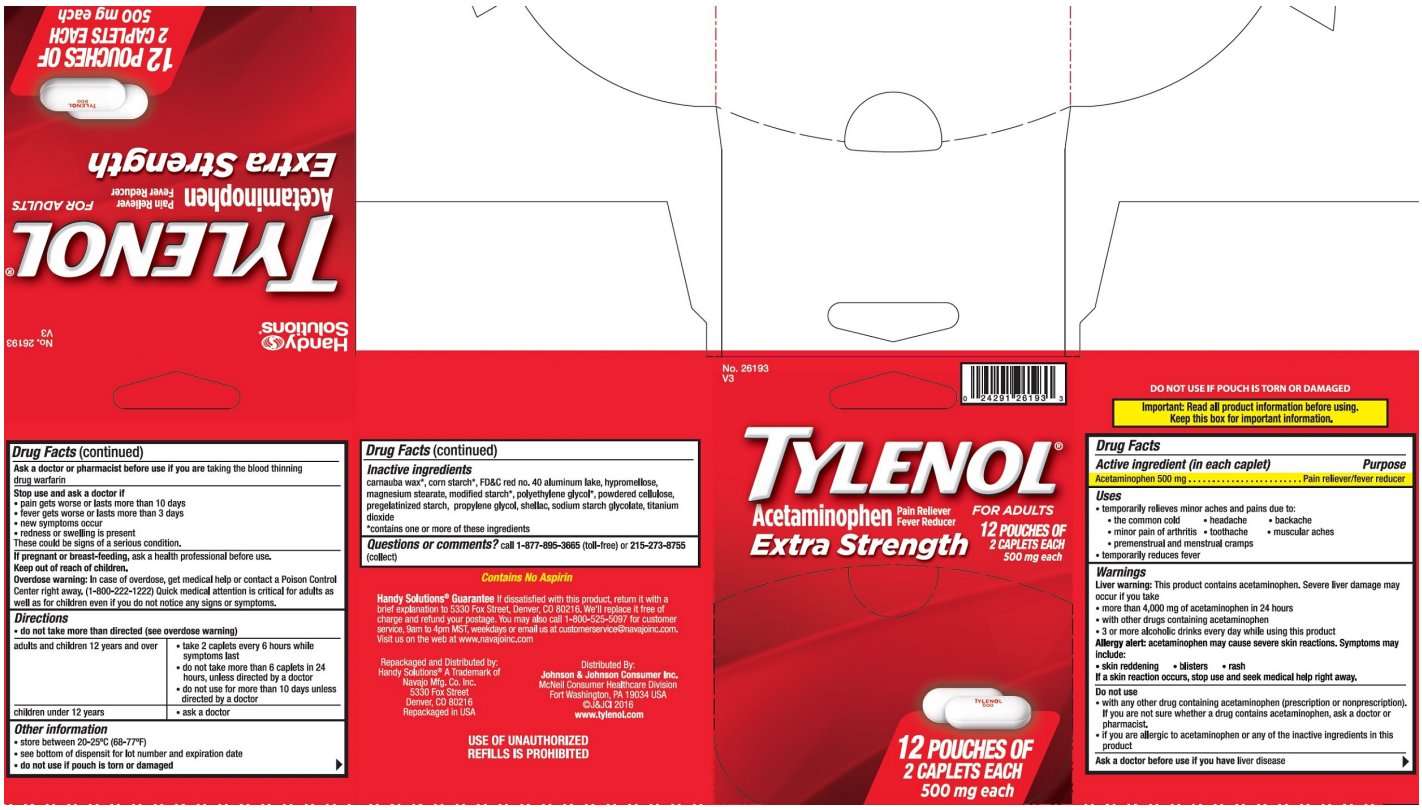
carnauba wax*, corn starch*, FD&C red no. 40 aluminum lake, hypromellose, magnesium stearate, modified starch, polyethylene glycol, powdered cellulose, pregelatinized starch, propylene glycol, shellac, sodium starch glycolate, titanium dioxide

*contains one or more of these ingredients

Questions or comments?

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

Package Labeling:



TYLENOL EXTRA STRENGTH

acetaminophen tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67751-167(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. 4 FREE ACID (UNII: WJE3T5596E)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
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:67751-167-03	2 in 1 POUCH	12/04/2017	03/31/2026
1		12 in 1 TRAY; 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	12/04/2017	

Labeler - Navajo Manufacturing Company Inc. (091917799)

Establishment

Name	Address	ID/FEI	Business Operations
Navajo Manufacutring Company Inc.		136941411	relabel(67751-167) , repack(67751-167)

Revised: 4/2024 Navajo Manufacturing Company Inc.