TYLENOL EXTRA STRENGTH- acetaminophen tablet, film coated
Navajo Manufacturing Company Inc.

Tylenol Extra Strength

Drug Facts

Active ingredients (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 fevers

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)

• see bottom of carton for lot number and expiration date
• do not use if pouch is opened

Inactive ingredients

carnauba wax*, corn starch, FD&C red no. 40 aluminum lake, hypromellose, magnesium stearate, 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. 40 (UNII: WZB9127XOA)	
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:67751-167-01	1 in 1 CARTON	09/22/2016	
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:67751-167-02	1 in 1 CARTON	09/22/2016	
2		4 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:67751-167-04	12 in 1 TRAY	09/22/2016	03/31/2026
3		1 in 1 POUCH; 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	09/22/2016	

Labeler - Navajo Manufacturing Company Inc. (091917799)

Establishment

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

Revised: 4/2024 Navajo Manufacturing Company Inc.