TYLENOL EXTRA STRENGTH- acetaminophen tablet, film coated
Savings Distributors LLC

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

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 menstual 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

Ifa 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 ■ take 2 capletes every 6 hours while symptoms

12 years and over: last
■ do not take more than 6 capletes 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 20-25C (68-77F)

■ **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:73097-012(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**
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
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)	
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:73097-012-02	1 in 1 CARTON	07/22/2019	
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:73097-012-40	20 in 1 CARTON	07/22/2019	
2		2 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:73097-012-50	25 in 1 BOX	07/22/2019	
3		2 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 not final	part343	07/22/2019	

Labeler - Savings Distributors LLC (010527359)

Establishment

Name	Address	ID/FEI	Business Operations
Savings Distributors LLC		010527359	repack(73097-012)

Revised: 7/2019 Savings Distributors LLC