TYLO EXTRA- acetaminophen tablet, delayed release America Medic & Science, LLC

Tylo Extra 500 mg

Tylo Extra 500 mg Drug Facts

Active Ingredient

Acetaminophen 500 mg

Purpose

Pain reliever/fever reducer

Uses

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

Do not use

- with any other drug containing acetaminophen (prescription or non prescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you have ever had an allergic reaction to acetaminophen or any of the inactive ingredients in this product.

Ask a doctor before use if you have liver disease

Ask your 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 appear
- 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

Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. 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 4 to 6 hours
- Do not take more than 8 caplets of this product in 24 hours.

Children under 12 years:

• do not use this product in children under 12 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage.

Inactive ingredients

CARNAUBA WAX
HYPROMELLOSES
POLYETHYLENE GLYCOL, UNSPECIFIED (
POVIDONE
CROSPOVIDONE
STEARIC ACID
TITANIUM DIOXIDE
STARCH, CORN

Other information

- store at 25°C (77°F)
- see end panel for lot number and expiration date

Questions or comments?

call toll free 1-855-470-6722

Package Labeling:

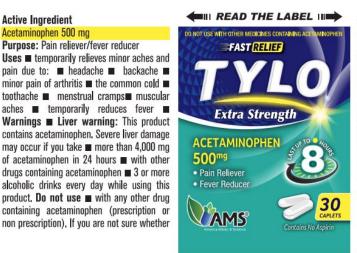




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> Manufactured by Elvi Pharma, LLC for America Medic & Science, (AMS), USA www.AmericaMedic.com

TYLO EXTRA

acetaminophen tablet, delayed release

Product Information

HUMAN OTC DRUG Item Code (Source) NDC:49638-110 **Product Type**

ORAL **Route of Administration**

Active Ingredient/Active Moiety

Basis of Strength Strength Ingredient Name

ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D) **ACETAMINOPHEN** 500 mg

Inactive Ingredients		
Ingredient Name	Strength	
CARNAUBA WAX (UNII: R12CBM0EIZ)		
HYPROMELLOSES (UNII: 3NXW29V3WO)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
POVIDONE (UNII: FZ 989GH94E)		
CROSPOVIDONE (UNII: 2S7830E561)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		
STARCH, CORN (UNII: 08232NY3SJ)		

Product Characteristics					
Color	white	Score	no score		
Shape	CAPSULE	Size	8mm		
Flavor		Imprint Code			
Contains					

Packaging					
# Item Code	Package Description	Marketing Start Date	Marketing End Date		
NDC:49638-110-	1 in 1 CARTON	01/17/2019			
1	30 in 1 BOTTLE; 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	01/17/2019		
	M013	01/17/2019		

Labeler - America Medic & Science, LLC (071065464)

Registrant - America Medic & Science, LLC (071065464)

Revised: 2/2024 America Medic & Science, LLC