

TYLO EXTRA STRENGTH- acetaminophen tablet
America Medic

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.

DRUG FACTS

Acetaminophen

Keep out of reach of children. In case of overdose, get medical help right away and contact a poison control center right away.

Oral Analgesic

Adults and children 12 years and over: Take 2 tablets at bedtime (Do not take more than 2 tablets in a 24 hour time)

Povidone
pregelatinized starch
stearic acid

Oral analgesic.

Do not use this product if you have had an allergic to Acetaminophen or any of the inactive ingredients. Ask a doctor before taking this product if you have Liver disease or are taking blood thinning medication. Do not take more than directed. If pregnant or breast feeding contact a doctor before using this product. Stop use and consult a doctor if: Pain gets worse or last more than 10 days: If fever gets worse or last more than 3 days: new symptoms appear: redness or swelling appear.



Drug Facts (continued)

- 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:** 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. (1800-222-1222) Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Drug Facts (continued)

Directions

- do not take more than directed (see overdose warning).

Adults and children 12 years and over:

- take 2 caplets at bedtime
- do not take more than 2 caplets of this product in 24 hours.

Children under 12 years:

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

Other information

- store between 20-25°C (68-77°F)
- do not use if neck wrap or foil inner seal imprinted with "Safety Seal®" is broken or missing
- see end panel for lot number and expiration date

Inactive ingredients

povidone, pregelatinized starch, stearic acid

Questions or comments?
call toll free 1-855-314-1850

See warnings information NDC 76168-010-10

TYLO EXTRA STRENGTH

Acetaminophen 500mg
Pain Reliever • Fever Reducer
Contains No Aspirin

60 CAPLETS - 500 mg each

Compares to active ingredients in Tylenol® Extra Strength

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
 - the common cold
 - toothache
 - menstrual cramps
 - muscular aches
- 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.

Do not use

- with any other drug containing acetaminophen (prescription or not prescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

Made in the USA

Made exclusively by CIBypharm for American Medic (AMS)
www.AmericanMedic.net, Seattle, Washington, USA

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

image of carton

TYLO EXTRA STRENGTH

acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49638-002
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
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white (white film)	Score	no score
Shape	OVAL (TABLET)	Size	17mm
Flavor		Imprint Code	C15
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49638-002-03	1 in 1 BOX		
1	NDC:49638-002-02	60 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	05/15/2012	

Labeler - America Medic (071065464)

Establishment

Name	Address	ID/FEI	Business Operations
America Medic		071065464	relabel, repack

Establishment

Name	Address	ID/FEI	Business Operations
Cispharma, Inc.		833171445	manufacture

