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.

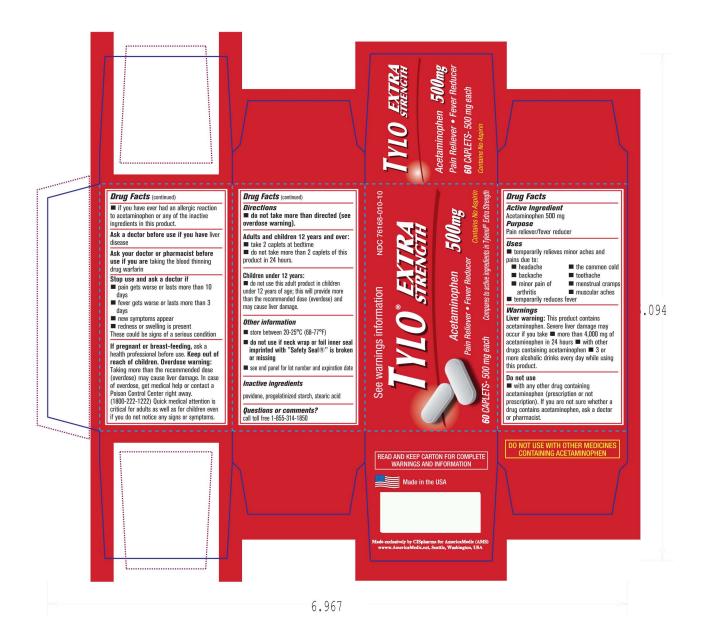
Oral Analgesic

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.



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)	Ac eta mino phen	500 mg

Inactive Ingredients		
Ingredient Name	Strength	
PO VIDO NE (UNII: FZ989 GH94E)		
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			
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date
:	NDC:49638-002-03	1 in 1 BOX		
	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

Revised: 5/2012 America Medic