

EXTRA STRENGTH PAIN RELIEVER- acetaminophen tablet
Mechanical Servants 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.

ACTIVE INGREDIENT IN EACH TABLET-

Acetaminophen 500 mg

Analgesic, Antipyretic (fever reducer)

Uses: temporarily relieves minor aches and pains due to: • headache • common cold • toothache • backache • muscular aches • menstrual cramps • minor arthritis pain

Temporarily reduces fever

Warnings:

Liver Warning: This product contains acetaminophen. Severe liver damage may occur if you take: • more than 8 tablets in 24 hours, which is the maximum daily amount • with other drugs containing acetaminophen (prescription or non-prescription). Ask a doctor or pharmacist before using with other drugs if you are not sure. • you have 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 product containing acetaminophen this will provide more than the recommended dose (overdose) of acetaminophen and could cause serious health concerns.

When using this product do not exceed recommended dose.

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 or fever persists or gets worse or lasts for more than 10 days • fever gets worse or lasts for 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. In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions:

Adults and children 12 years of age and older: Take 2 tablets every 4 to 6 hours as

needed, do not exceed 8 tablets in 24 hours, or as directed by a doctor.

Children under 12 years: consult a doctor

Inactive Ingredients: corn starch, hydroxypropyl methylcellulose*, maltodextrin*, polyethylen glycol*, microcrystalline cellulose, povidone, sodium starch glycolate, stearic acid

*contains one or more of these ingredients

Extra Strength

PAIN RELIEVER

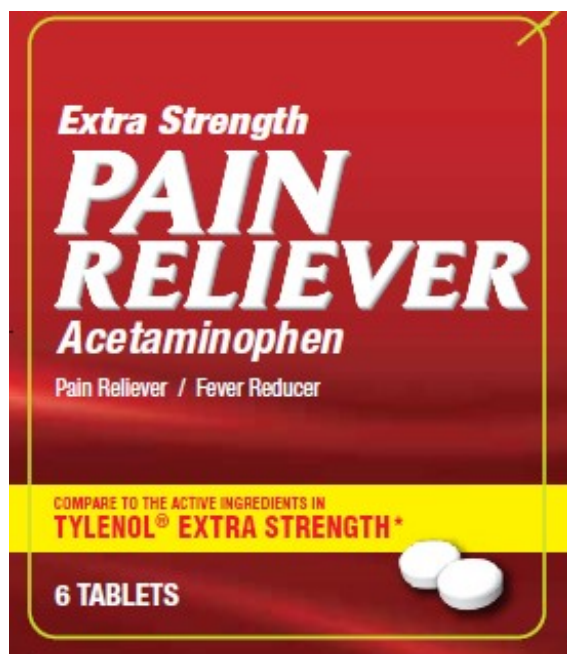
Acetaminophen

Pain Reliever / Fever Reducer

COMPARE TO THE ACTIVE INGREDIENTS IN

TYLENOL® EXTRA STRENGTH*

6 TABLETS



EXTRA STRENGTH PAIN RELIEVER

acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:29485-7626
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	12mm
Flavor		Imprint Code	FR1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:29485-7626-6	3 in 1 PACKET	03/15/2019	
1		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	03/15/2019	

Labeler - Mechanical Servants LLC (005530951)

Revised: 10/2021

Mechanical Servants LLC