

EXTRA STRENGTH ACETAMINOPHEN- acetaminophen tablet
TIME CAP LABORATORIES, INC.

**697R Timely 49483-697 Extra Strength Acetaminophen 500 mg Rapid Release
400 count**

DRUG FACTS

Active ingredient (in each caplet)

Acetaminophen 500 mg

Purpose

Pain reliever/fever reducer

Uses

temporarily relieves minor aches and pains due to:

- headache
 - muscular aches
 - backache
 - minor pain of arthritis
 - the common cold
 - toothache
 - premenstrual and menstrual 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

If a 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 12 years and over:

- take 2 caplets every 6 hours while symptoms last
- do not take more than 6 caplets 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 20-25°C (68-77°F)

Inactive ingredients croscarmellose sodium, crospovidone, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, magnesium stearate, mica based pearlescent pigment, polyethylene glycol 400, polyethylene glycol 6000, polysorbate 80, povidone, pregelatinized starch

Questions or comments? Call **1-877-290-4008**

NDC 49483-697-43

timely™

¹Compare to the active ingredient in Extra Strength Tylenol® Rapid Release Gels


Extra Strength

Rapid Release

Acetaminophen 500 mg

Pain Reliever/Fever Reducer

Fast Relief



actual size

for adults

400 CAPLETS - 500 mg EACH

TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING

Drug Facts

Active ingredient (in each caplet) **Purpose**
Acetaminophen 500 mg. Pain reliever/fever reducer

Uses
■ temporarily relieves minor aches and pains due to:
■ headache ■ muscular aches
■ backache ■ minor pain of arthritis
■ the common cold ■ toothache
■ menstrual and menstrual 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
If a 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

Drug Facts (continued)
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 caplets every 6 hours while symptoms last

Drug Facts (continued)
12 years and over ■ do not take more than 6 caplets 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 20-25°C (68-77°F)
Inactive ingredients croscarmellose sodium, crospovidone, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, magnesium stearate, mica based pearlescent pigment, polyethylene glycol 400, polyethylene glycol 6000, polysorbate 80, povidone, pregelatinized starch
Questions or comments?
Call **1-877-290-4008**
¹This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., owner of the registered trademark Extra Strength Tylenol® Rapid Release Gels.
Distributed by: Time-Cap Labs, Inc.
7 Michael Avenue, Farmingdale, NY 11735
687R 0222 Made in India

Lot No.: **Varnish Omit Area**
Exp. Date:

EXTRA STRENGTH ACETAMINOPHEN

acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49483-697
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
FD&C YELLOW NO. 6 ALUMINUM LAKE (UNII: GYP6Z2JR6Q)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPVIDONE (UNII: 2S7830E561)	
FD&C RED NO. 40 ALUMINUM LAKE (UNII: 6T47AS764T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
MICA (UNII: V8A1AW0880)	
POVIDONE K30 (UNII: U725QWY32X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	red	Score	no score
Shape	CAPSULE (biconvex tablets)	Size	17mm
Flavor		Imprint Code	TCL;A71
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49483-697-43	400 in 1 BOTTLE; Type 0: Not a Combination Product	02/11/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC Monograph Drug	M013	02/11/2022	
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Labeler - TIME CAP LABORATORIES, INC. (037052099)

Registrant - TIME CAP LABORATORIES, INC. (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	manufacture(49483-697)

Revised: 2/2025

TIME CAP LABORATORIES, INC.