

ACETAMINOPHEN EXTRA STRENGTH- acetaminophen tablet, film coated
TIME CAP LABS INC

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.

341R TCL 49483 341 Acetaminophen 500 mg 100ct 500ct

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

the common cold

backache

minor pain of arthritis

toothache

muscular aches

premenstrual and menstrual cramps

- temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 8 caplets in 24 hours, which is the maximum daily amount
- 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
- for more than 10 days for pain unless directed by a doctor

- for more than 3 days for fever unless directed by a doctor

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 using and ask a doctor if

- symptoms do not improve
- new symptoms occur
- pain or fever persists or gets worse

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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: do not take more than directed

adults and children 12 years and over:

- take 2 caplets (1,000 mg) every 6 hours while symptoms last
- do not take more than 6 caplets (3,000 mg) 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

Other information

- SODIUM FREE
- store at 25°C (77°F) excursions permitted between 15°-30°C (59°-86°F)
- use by expiration date on package

hypromellose, mineral oil, povidone, pregelatinized starch, sodium starch glycolate*, stearic acid, titanium dioxide

* may contain this ingredient

NDC 49483-341-50
*Compare to the active ingredient in Extra Strength Tylenol®



Extra Strength Pain Reliever

Acetaminophen 500 mg

Pain Reliever / Fever Reducer

For Adults



500 CAPLETS**
Actual Size

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	Purpose
Active ingredient (in each caplet) Acetaminophen 500 mg	Pain reliever/fever reducer
Uses	
<ul style="list-style-type: none">Temporarily relieves minor aches and pains due to:<ul style="list-style-type: none">headachebackachemuscular achesTemporarily reduces fever	
Warnings	
Liver warnings: This product contains acetaminophen. Severe liver damage may occur if you take: <ul style="list-style-type: none">more than 8 caplets in 24 hours, which is the maximum daily amountwith other drugs containing acetaminophen3 or more alcoholic drinks a day while using this product Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: <ul style="list-style-type: none">feverhivesskin rashswelling If a skin reaction occurs, stop use and seek medical help right away.	
Do not use	
<ul style="list-style-type: none">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 taking acetaminophen product prescribed for you or any other of the inactive ingredients for more than 10 days for pain unless directed by a doctor	

Drug Facts (continued under label)

This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Extra Strength Tylenol®. Manufactured by:
Time-Cap Labs, Inc.
7 Michael Avenue
Farmingdale, NY 11735



3 49483 34150 8

Lot No.:
Exp. Date:

Varnish Omit Area

Drug Facts (continued)
<ul style="list-style-type: none">for more than 3 days for fever unless directed by a doctor Ask a doctor before use if you have liver disease
Ask a doctor or pharmacist before use if you are <ul style="list-style-type: none">taking the blood thinning drug warfarin
Stop using and ask a doctor if <ul style="list-style-type: none">symptoms do not improvenew symptoms occursymptoms do not improve or get worse
If pregnant or breast-feeding, ask a health professional before use
Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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 <ul style="list-style-type: none">Do not take more than directedadults and children<ul style="list-style-type: none">take 2 caplets (1,000 mg) every 4 hours while symptoms last, but not more than 8 caplets (3,000 mg) in 24 hours, unless directed by a doctordo not use for more than 10 days unless directed by a doctorchildren under 12 years: ask a doctor
Other information <ul style="list-style-type: none">SODIUM FREEstore at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)use by expiration date on package
Inactive ingredients hypromellose, mineral oil, povidone, pregelatinized starch, sodium starch glycolate, stearic acid, titanium dioxide. Some capsules may contain this ingredient
Questions or comments? call 1-877-298-4008

NDC 49483-341-01

Time-Cap Labs, Inc.
 *Compare to the active ingredient in Extra Strength Tylenol®

ACETAMINOPHEN

EXTRA STRENGTH

Pain Reliever / Fever Reducer



Contains no aspirin

100 CAPLETS - 500 mg each
 (Capsule-Shaped Tablet)

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 341R 0417

Manufactured by:
 Time-Cap Labs, Inc.
 Michael Avenue
 Farmingdale, NY 11735

Drug Facts

Active Ingredient (in each caplet) Acetaminophen 500 mg

Purpose Pain reliever/fever reducer

Uses

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

Warnings

Liver warnings: This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 6 caplets in 24 hours, which is the maximum daily amount
- 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 rash
- skin redness/itching, 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.

LOT NO.: _____
EXP. DATE: _____

STOP PEELING HERE

Drug Facts (continued)

- If you are allergic to acetaminophen or any of the inactive ingredients in this product
- for more than 10 days for pain unless directed by a doctor
- for more than 3 days for fever unless directed by a doctor

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 using and ask a doctor if:

- symptoms do not improve
- new symptoms occur
- pain or fever persists or gets worse

■ Pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Prompt medical attention is essential as well as for children even if you do not notice any signs or symptoms.

Directions

- do not take more than directed
- take 2 caplets (1,000 mg) every 6 hours while symptoms last
- do not take more than 6 caplets (3,000 mg) 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 ■ **SODIUM FREE**

- score at 25°C (77°F) excursions permitted between 15-30°C (59-86°F)
- use by expiration date on package

Inactive ingredients: hypromellose, mineral oil, polydioxane, polyethylene glycol, sodium starch glycolate, stearic acid, titanium dioxide

STOP PEELING

ACETAMINOPHEN EXTRA STRENGTH

acetaminophen tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49483-341
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
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MINERAL OIL (UNII: T5L8T28FGP)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	

Product Characteristics

Color	white	Score	no score
Shape	OVAL ((caplet))	Size	17mm
Flavor		Imprint Code	TCL341
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49483-341-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/17/2018	
2	NDC:49483-341-50	500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/20/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	07/18/2011	

Labeler - TIME CAP LABS INC (037052099)

Registrant - TIME CAP LABS INC (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
TIME CAP LABS INC		037052099	manufacture(49483-341)

Revised: 5/2021

TIME CAP LABS INC