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

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### 341R TCL 49483 341 Extra Strength Acetaminophen 500 mg

#### **DRUG FACTS**

#### Active ingredient (in each caplet)

Acetaminophen 500 mg

#### **Purpose**

Pain reliever/fever reducer

#### Uses

temporarily relieves minor aches and pains due to:

- the common cold
- headache
- 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 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 using 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 (1-800-222-1222) right away. 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 waning) 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 take for more than 10 days unless directed by a doctor

children under 12 years: ask a doctor

#### OTHER INFORMATION

#### Other information

- SODIUM FREE
- store between 20-25°C (68-77°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 glycloate\*, stearic acid, titanium dioxide \*may contain this ingredient

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

# if you are allergic to acetaminophen or any of the inactive ingredients in this product Ask a doctor or pharmacist before use if you are taking the Ask a doctor before use if you have liver disease olood thinning drug warfarin

**Drug Facts** (continued)

Varnish Omit Area

Exp. Date Lot No .:

341R 1023

 new symptoms occur
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 These could be signs of a serious condition. Stop use and ask a doctor if
pain gets worse or lasts more than 10 days
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do not take more than 6 caplets in

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do not take for more than 10 days unless directed by a doctor

12 years and over

adults and children

■ take 2 caplets every 6 hours while

Do not take more than directed. See overdose warning

Directions

children under 12 years ask a doctor

Other information

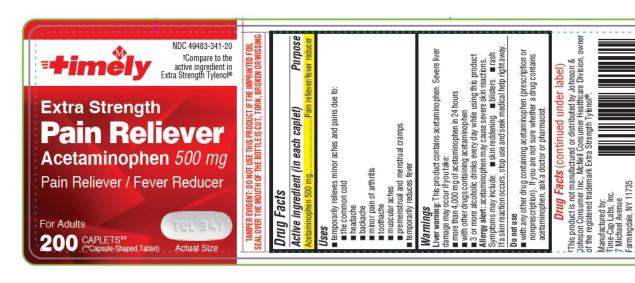
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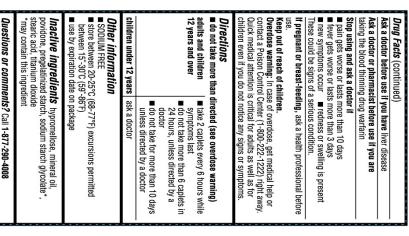
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Adhesive Area





341R 0922

7 Michael Avenue Farmingdale, NY 11735

Time-Cap Labs, Inc.

Manufactured by:

Varnish Omit Area

Date Lot No.:

Exp.

This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Extra Strength Tylenol®

**Drug Facts** (continued under label)



Adhesive Area

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

Active ingredient (in each caplet) Orug Facts



.iver warning: This product contains acetaminophen. Severe liver

damage may occur if you take:

more than 4,000 mg of acetaminophen in 24 hours

■ minor pain of arthritis ■ toothache
■ muscular aches ■ premenstrual and menstrual cramps temporarily reduces fever

■ temporarily relieves minor aches and pains due to: ■ the common cold ■ headache ■ backache

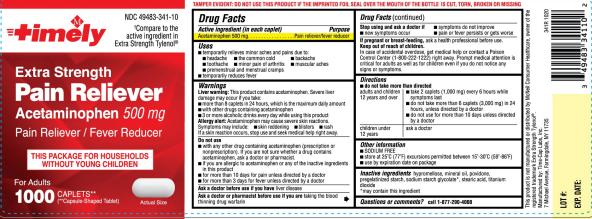
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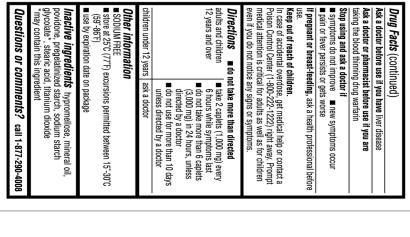
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■ if you are allergic to acetaminophen or any of the inactive

ingredients in this product







## **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	<b>Basis of Strength</b>	Strength
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	500 mg

Inactive Ingredients	
Ingredient Name	Strength

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)		
HYPROMELLOSES (UNII: 3NXW29V3WO)		

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

P	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		
3	NDC:49483- 341-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	01/20/2022		
4	NDC:49483- 341-20	200 in 1 BOTTLE; Type 0: Not a Combination Product	10/25/2023		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	07/18/2011	

## Labeler - TIME CAP LABS INC (037052099)

# Registrant - TIME CAP LABS INC (037052099)

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

Revised: 10/2023 TIME CAP LABS INC