

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

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 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 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 glycolate*, stearic acid, titanium dioxide

*may contain this ingredient

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

341R- Timely APAP 500mg 100ct label

Della Fasano (continuado)

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

If pregnant or breast-feeding, ask a health professional

**Keen out of reach of children
before use.**

Overdose warning: In case of overdose, get medical help or call poison control.

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.

adults and children ■ take 2 caplets every 6 hours

■ 12 years and over while symptoms last do not take more than

■ 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

children under 12 years old

children under 12 years | ask a doctor

Other information

SODIUM FREE
store between 30-35°C (68-77°F) avoid freezing

■ Store between 20-25°C (68-77°F) except disinfectants permitted between 15-30°C (59-86°F)

■ use by expiration date on package

Inactive ingredients hypromellose, mineral oil,

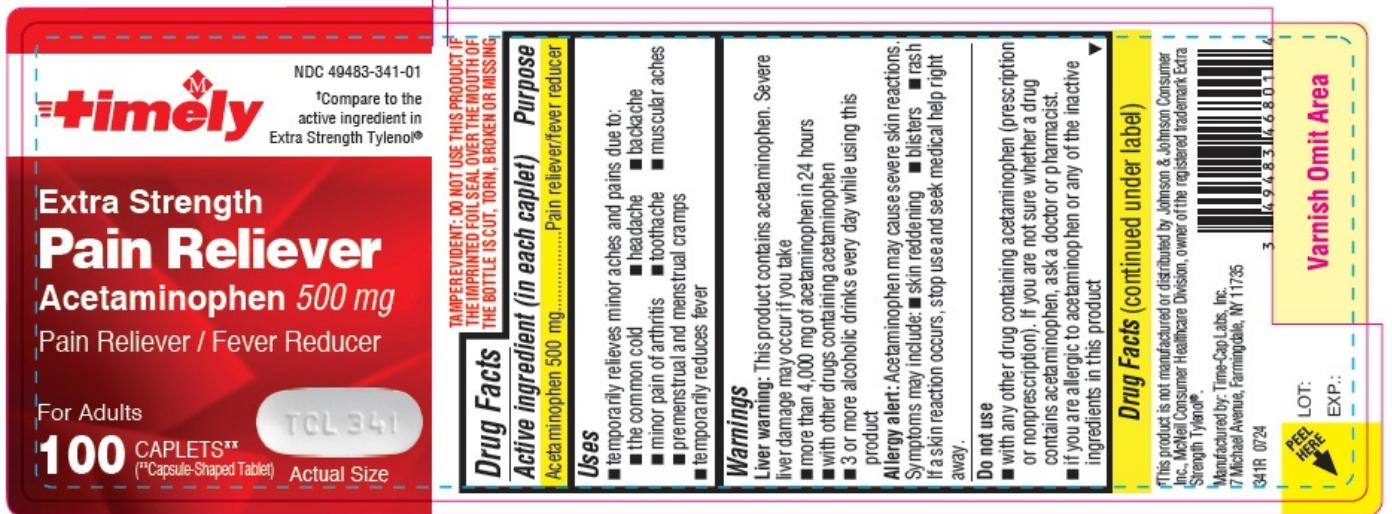
povidone, pregelatinized starch, sodium starch glycolate*,
stearic acid, titanium dioxide

*Stearic acid, titanium dioxide
*may contain this ingredient

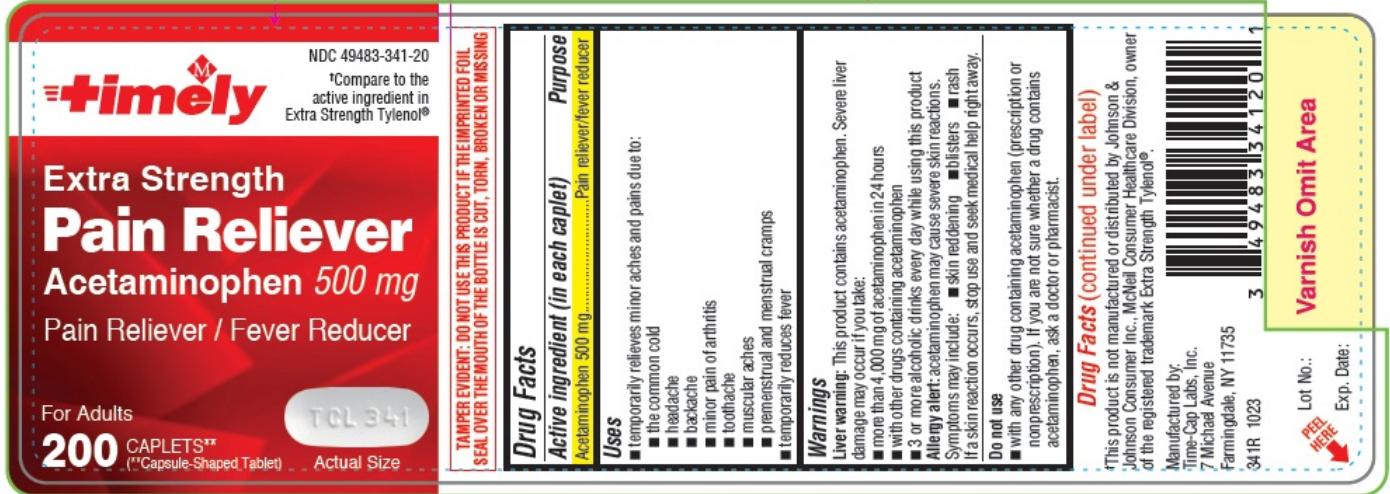
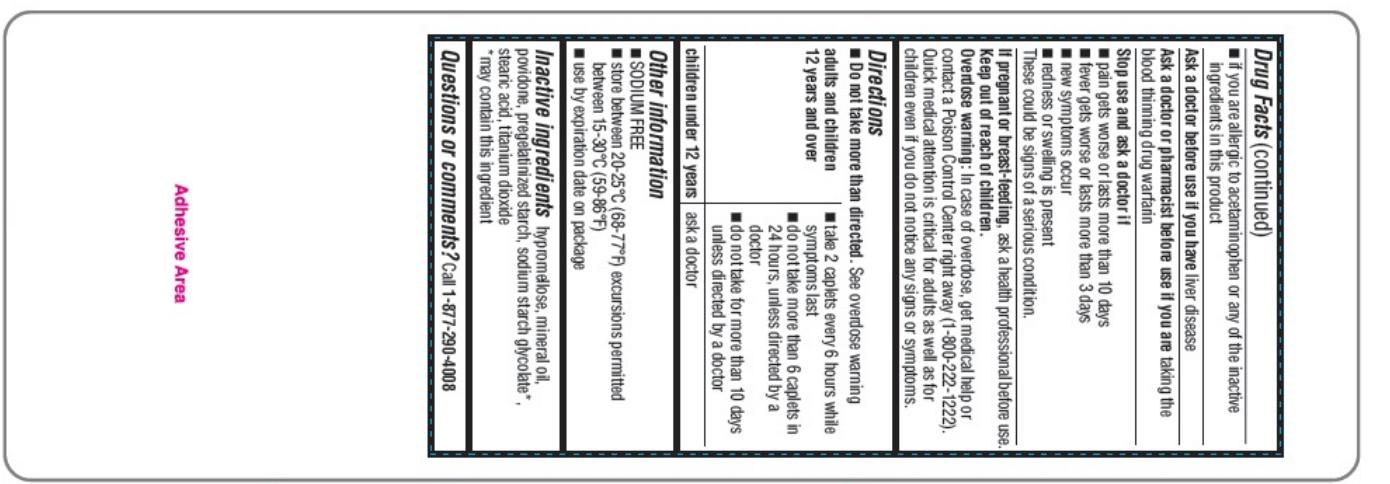
Questions or comments? Call 1-877-280-1008

www.ams.org/proc/2000-000-000-0000-00000

Adhesive Area



341R- Timely APAP 500mg 200ct label



341R- Timely APAP 500mg 500ct label

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
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)	
HYDROMELLOSES (UNII: 3NXW29V3WO)	

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	
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	Business Operations
TIME CAP LABS INC		037052099	manufacture(49483-341)

Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		677604129	manufacture(49483-341)

Revised: 6/2025

TIME CAP LABS INC