

**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 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**



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

**timely**

**Extra Strength Pain Reliever**  
**Acetaminophen 500 mg**  
 Pain Reliever / Fever Reducer

For Adults  
**500** CAPLETS\*\*  
 (\*\*Capsule-Shaped Tablet) 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**  
**Active ingredient (in each caplet)**  
 Acetaminophen 500 mg. 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 8 caplets in 24 hours  
 more than 3,000 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

**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  
 341R 0922  
 3 49483 34110 2

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

Adhesive Area

**Drug Facts (continued)**  
**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  
 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**  
 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

NDC 49483-341-10  
 Compare to the active ingredient in Extra Strength Tylenol®

**timely**

**Extra Strength Pain Reliever**  
**Acetaminophen 500 mg**  
 Pain Reliever / Fever Reducer

For Adults  
**1000** CAPLETS\*\*  
 (\*\*Capsule-Shaped Tablet) Actual Size

**THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN**

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)**  
 Acetaminophen 500 mg. Pain reliever/fever reducer.

**Uses**  
 Temporarily relieves minor aches and pains due to:  
 the common cold ■ headache ■ backache  
 toothache ■ minor pain of arthritis ■ 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

**Drug Facts (continued)**  
**Stop using and ask a doctor if**  
 new symptoms occur ■ symptoms do not improve  
 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  
 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  
 store 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  
 \* may contain this ingredient

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

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  
 341R 1020  
 3 49483 34110 2

**LOT #:**  
**EXP. DATE:**



NDC 49483-341-01  
<sup>1</sup>Compare to the active ingredient in Extra Strength Tylenol®

**Extra Strength Pain Reliever**  
**Acetaminophen 500 mg**  
 Pain Reliever / Fever Reducer

For Adults  
**100** CAPLETS\*\*  
(\*\*Capsule-Shaped Tablet)

**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)** Acetaminophen 500 mg. **Pain reliever/fever reducer**

**Uses**

- temporarily relieves minor aches and pains due to:
  - headache
  - the common cold
  - minor pain of arthritis
- backache
- 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 redness ■ 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

**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.  
 71 Michael Avenue  
 Farmingdale, NY 11735  
 341R 1020

Lot No.:  
**FREE HERE**   
Exp. Date:



49483 34101 0  
 3

**Drug Facts (continued)**

**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
  - 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
- store 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

\* may contain this ingredient

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

# 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

<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>SODIUM STARCH GLYCOLATE TYPE A CORN</b> (UNII: AG9B65PV6B)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	

### Product Characteristics

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

### 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)