

## **ACETAMINOPHEN- acetaminophen tablet**

### **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.*

-----

## **340R Timely 49483-340 Acetaminophen 325 mg Tablets**

### **DRUG FACTS**

#### ***Active ingredient (in each tablet)***

Acetaminophen 325 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. The maximum daily dose of this product is 10 tablets (3,250 mg) in 24 hours for adults or 5 tablets (1,625 mg) in 24 hours for children. Severe liver damage may occur if

- adult takes more than 4,000 mg of acetaminophen in 24 hours
- child takes more than 5 doses in 24 hours, which is the maximum daily amount
- taken with other drugs containing acetaminophen
- adult has 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 the user has** liver disease

**Ask a doctor or pharmacist before use if the user is** taking the blood thinning drug warfarin

**Stop use and ask a doctor if**

- pain gets worse or lasts more than 10 days in adults
- pain gets worse or lasts more than 5 days in children under 12 years
- 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 tablets every 4 to 6 hours while symptoms last
- do not take more than 10 tablets in 24 hours, unless directed by a doctor
- do not use for more than 10 days unless directed by a doctor

**children 6 years to under 12 years**

- take 1 tablet every 4 to 6 hours while symptoms last
- do not take more than 5 tablets in 24 hours
- do not use for more than 5 days unless directed by a doctor

**children under 6 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

### ***Inactive ingredients***

povidone, pregelatinized starch, sodium starch glycolate\*, stearic acid

\*may contain this ingredient

NDC 49483-340-10  
\*Compare to the active ingredient in  
Tylenol® Regular Strength

**timely™**

Regular Strength

**Pain Reliever  
Acetaminophen 325 mg**

Pain Reliever / Fever Reducer

Contains no aspirin

**THIS PACKAGE FOR HOUSEHOLDS  
WITHOUT YOUNG CHILDREN**

**1000** TABLETS

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 tablet)**

Acetaminophen 325 mg...Pain reliever/fever reducer

**Purpose**

#### 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. The maximum daily dose of this product is 10 tablets (3,250 mg) in 24 hours for adults or 5 tablets (1,625 mg) in 24 hours for children. Severe liver damage may occur if:

- adult takes more than 4,000 mg of acetaminophen in 24 hours
- child takes more than 5 doses in 24 hours, which is the maximum daily amount
- taken with other drugs containing acetaminophen
- adult has 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.

### Drug Facts (continued)

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 the user has liver disease**

**Ask a doctor or pharmacist before use if the user is taking the blood thinning drug warfarin**

#### Stop use and ask a doctor if

- pain gets worse or lasts more than 10 days in adults
  - pain gets worse or lasts more than 5 days in children under 12 years
  - 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

### Drug Facts (continued)

not notice any signs or symptoms.

#### Directions

See overdose warning

**adults and children 12 years and over**

- Do not take more than directed.
- take 2 tablets every 4 to 6 hours while symptoms last
- do not take more than 10 tablets in 24 hours, unless directed by a doctor
- do not use for more than 10 days unless directed by a doctor

**children 6 years to under 12 years**

- take 1 tablet every 4 to 6 hours while symptoms last
- do not take more than 5 tablets in 24 hours
- do not use for more than 5 days unless directed by a doctor

**children under 6 years**

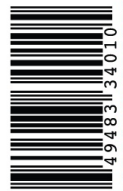
- ask a doctor

#### 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** povidone, pregelatinized starch, sodium starch glycolate\*, stearic acid \*may contain this ingredient

**Questions or comments?** Call 1-877-290-4008  
Manufactured by: Time-Cap Labs, Inc.,  
7 Michael Avenue, Farmingdale, NY 11735



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

### Drug Facts (continued)

**Ask a doctor before use if the user has liver disease**

**Ask a doctor or pharmacist before use if the user is taking the blood thinning drug warfarin**

**Stop use and ask a doctor if**

- pain gets worse or lasts more than 10 days in adults
  - pain gets worse or lasts more than 5 days in children under 12 years
  - 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

See overdose warning

- Do not take more than directed
- take 2 tablets every 4 to 6 hours while symptoms last
- do not take more than 10 tablets in 24 hours, unless directed by a doctor
- do not use for more than 10 days unless directed by a doctor

- children 6 years to under 12 years**
  - take 1 tablet every 4 to 6 hours while symptoms last
  - do not take more than 5 tablets in 24 hours
  - do not use for more than 5 days unless directed by a doctor
- children under 6 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** povidone, pregelatinized starch, sodium starch glycolate\*, stearic acid \*may contain this ingredient

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

**STOP PEEING**

**Adhesive Area**

NDC 49483-340-01  
\*Compare to the active ingredient in  
Regular Strength Tylenol®

**timely™**

Regular Strength

**Pain Reliever  
Acetaminophen 325 mg**

Pain Reliever /  
Fever Reducer

Contains no aspirin

**100** TABLETS

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 tablet)**  
Acetaminophen 325 mg...Pain reliever/fever reducer

#### Purpose

- 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. The maximum daily dose of this product is 10 tablets (3,250 mg) in 24 hours for adults or 5 tablets (1,625 mg) in 24 hours for children. Severe liver damage may occur if:

- adult takes more than 4,000 mg of acetaminophen in 24 hours
- child takes more than 5 doses in 24 hours, which is the maximum daily amount
- taken with other drugs containing acetaminophen
- adult has 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**

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

Manufactured by: Time-Cap Labs, Inc.,  
7 Michael Avenue Farmingdale,  
NY 11735 340R 1022



**Varnish Omit Area**

**Lot No.:**  
**Exp. Date:**

**PEEL HERE**

# ACETAMINOPHEN

acetaminophen tablet

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49483-340
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	TCL340
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49483-340-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/17/2018	
2	NDC:49483-340-10	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/03/2021	

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part343	12/15/2011	

**Labeler -** TIME CAP LABS INC (037052099)

Establishment			
Name	Address	ID/FEI	Business Operations
TIME CAP LABS INC		037052099	manufacture(49483-340)

Revised: 3/2023

TIME CAP LABS INC