ACETAMINOPHEN- acetaminophen tablet TIME CAP LABS INC

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



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 reduce

- 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 ■ rash If a skin reaction occurs, stop

children

unless directed by a doctor ■ do use for more than 10 days unless

do not

directed by a doctor

Drug Facts (continued)

use and seek medical help right away

Do not use

Purpose

- I 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.

Neep 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 symptom

Directions Do not take more than directed.

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

years to under 12 vears

- 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 ve

Other information ■ SODIUM FREE store at 25°C (77°F) excursions permitted between 15°-30°C (59°-86°F)

ask a doctor

■ use by expiration date on package

Inactive ingredients povidone, pregelatinized starch, sodium starch glycolate*, stearic acid *may contain this ingredient

†This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Regular Strength Tylenol®. 340R 1022

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

DATE

n

5

Adhesive Area

luestions or comments? all 1-877-290-4008

contain

Inactive ingredients povidone, pregelatinized starch, sodium starch glycolate*, stearic acid

use by

expiration date on

package

excursions permitted between

■ SODIUM FREE ■ store at 25°C itted between 15°-30°C (59°-86°F)

'Compare to the

active ingredient in

Tylenol® Regular Strength

information

STOP PEELING

12 years years to under under

ask a doctor

■ 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

Directions

adults and children 12 years ■ taxe 2 tablets every 4 to 6 hours while symptoms last ■ do not take more than 10 tablets in 24 hours, take 2 tablets every Do not take more than directed.

adults as well as for children even if you do not notice

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

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 rever gets worse or lasts more than 3 days new symptoms occur redness or swelling is present.

These could be signs of a serious condition. the blood thinning drug wartarin

Drug Facts (continued

)harmacist drug contains a cetamin ophen. f the inactive ingredients in this product ■ if you are

ksk a doctor before use if the user has liver disease ophen, ask a doctor or aller gic to acetaminophen or any

Ask a doctor or pharmacist before use if the user is

Regular Strength

Pain Reliever Acetaminophen 325 mg

Pain Reliever / Fever Reducer

Contains No Aspirin

100 TABLETS



Purpose

Active ingredient (in each tablet,

Drug Facts

 premenstrual and menstrual cramps reduces fever mporarily relieves minor aches and pains due headache muscular aches backache minor pain of arthritis tete common cold toothache temporarily

temporarily

Ner

warning: This product contains acetaminophen.

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

acetaminophen

adult has 3 or more alcoholic drinks every day while using this product Allergy alert: Acetaminophen may cause severe skin reactions. 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 fo in 24 hours for adults or 5 tablets (1,525 mg

adult takes

Symptoms may include: skin reddening blisters rash If a skin reaction occurs, stop use and seek medical help right away with any other drug containing a cetaminophen notuse prescription or nonprescription). If you are not sure whether ◀

This product is not manufactured or distributed by Johnson & Johnson Consumer Michael Consumer Healthcare Division , owner of the registered trademark Tylend® McNeil Consumer Healthcare Division, Regular Strength. Drug





Varnish Omit Area

ACETAMINOPHEN

acetaminophen tablet

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:49483-340

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D)

ACETAMINOPHEN

325 mg

Inactive Ingredients			
Ingredient Name	Strength		
POVIDONE (UNII: FZ 989GH94E)			
STARCH, CORN (UNII: O8232NY3SJ)			
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)			
STEARIC ACID (UNII: 4ELV7Z65AP)			

Product Characteristics			
Color	white	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	TCL340
Contains			

ı	P	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			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	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: 2/2025 TIME CAP LABS INC