

ACETAMINOPHEN- acetaminophen tablet, film coated
TIME CAP LABORATORIES, 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.

342R APAP

Active Ingredient: Each tablet contains Acetaminophen 500 mg

PURPOSE: Pain Reliever - fever reducer

Keep Out of the Reach of Children: In case of overdose, get medical help or contact a Poison Control Center right away

INDICATIONS AND USAGE:

Pain Reliever – temporarily relieves minor aches and pains due to: the common cold, headache, backache, muscular aches, toothache, premenstrual and menstrual cramps, minor pain of arthritis. Temporarily reduces fever.

Warnings;

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take more than 8 tablets in 24 hours, which is the maximum daily amount; 3 or more alcoholic drinks every day while using this product; with other drugs containing acetaminophen.

Overdose warning: Taking more than the recommended dose (Overdose) may cause liver damage. in case of overdose, get medical help or contact a Poison Control Center (1-800-222-1221) right way. Quick medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.

Do not take more than directed (see overdosage warning)

Adults and children 12 years and over: take 2 tablets (1,000 mg) every 6 hours while symptoms last; do not take more than 6 tablets (3,000 mg) 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: Do not use this adult extra strength product in children under 12 years of age, this will provide more than the recommended dose (overdosage) of acetaminophen and may cause liver damage

CARNAUBA WAX, FD-C RED NO. 40 ALUMINUM LAKE, HYPROMELLOSE, POLYETHYLENE GLYCOL(PEG) 400, POLYETHYLENE GLYCOL (peg) 8000, POVIDONE, PREGELATINIZED STARCH, SODIUM STARCH GLYCOLATE**, STEARIC ACID, SUCRALOSE, TITANIUM DIOXIDE

** MAY CONTAIN THIS INGREDIENT

LOT #: _____
EXP. DATE: _____

FEEL HERE FOR MORE DRUG FACTS

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.
- 3 or more alcoholic drinks every day while using this product.
- with other drugs containing acetaminophen.

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take more than 8 tablets in 24 hours, which is the maximum daily amount.

Uses

Temporarily relieves minor aches and pains due to:

- the common cold
- headache
- muscle aches
- minor pain of arthritis
- menstrual cramps
- toothache

Temporarily reduces fever.

Drug Facts

Active ingredient (in each tablet) Purpose
Acetaminophen 500 mg. Pain reliever/fever reducer

Directions

- do not take more than directed (see overdose warning)
- adults and children 12 years and over:
 - take 2 tablets (1,000 mg) every 6 hours while symptoms last
 - do not take more than 8 tablets (3,000 mg) 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:
 - do not use this adult extra strength product in children under 12 years of age, this will provide more than the recommended dose (overdose) of acetaminophen and may cause liver damage

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 carnauba wax, FD&C Red #40 aluminum lake, hydroxypropyl methylcellulose, polyethylene glycol, polyvidone, pregelatinized starch, sodium starch glycolate, stearic acid, sucralose, titanium dioxide *may contain this ingredient

STOP PEELING

Time-Cap Labs, Inc.
NDC-49483-342-01
Compare to the active ingredient in Extra Strength Tylenol® EZ TABS

ACETAMINOPHEN
EXTRA STRENGTH
Pain Reliever / Fever Reducer
Easy to Swallow
Contains no aspirin
100 TABLETS - 500 mg each

Manufactured by Time-Cap Labs, Inc.
7 Michael Avenue, Farmingdale, NY 11735
3429 1111

THIS PRODUCT IS NOT MANUFACTURED OR DISTRIBUTED BY McNEIL-CONSUMER HEALTHCARE, OWNER OF THE REGISTERED TRADEMARK EXTRA STRENGTH TYLENOL®.

TAPER EDGES: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING.

4 9 4 8 3 3 4 2 0 1 7

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 use and ask a doctor if ■ new symptoms occur
■ pain gets worse or lasts more than 10 days
■ fever gets worse or lasts more than 3 days
■ 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: Taking more than the recommended dose (overdose) may cause liver damage. 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

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 - do not take for more than 10 days unless directed by a doctor
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 - do not use this adult extra strength product in children under 12 years of age, this will provide more than the recommended dose (overdose) of acetaminophen and may cause liver damage

Other Information

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- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
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Inactive ingredients carnauba wax, FD&C Red #40 aluminum lake, hydroxypropyl methylcellulose, polyethylene glycol, polyvidone, pregelatinized starch, sodium starch glycolate, stearic acid, sucralose, titanium dioxide *may contain this ingredient

STOP PEELING

ACETAMINOPHEN
acetaminophen tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49483-342
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
CARNAUBA WAX (UNII: R12CBM0EIZ)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	red	Score	no score
Shape	ROUND	Size	11mm
Flavor		Imprint Code	TCL342
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49483-342-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/17/2018	
2	NDC:49483-342-10	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/17/2018	
3	NDC:49483-342-00	100000 in 1 CARTON; Type 0: Not a Combination Product	12/17/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	05/01/2012	

Labeler - TIME CAP LABORATORIES, INC (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
TIME CAP LABORATORIES, INC		037052099	manufacture(49483-342)

Revised: 12/2018

TIME CAP LABORATORIES, INC