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.

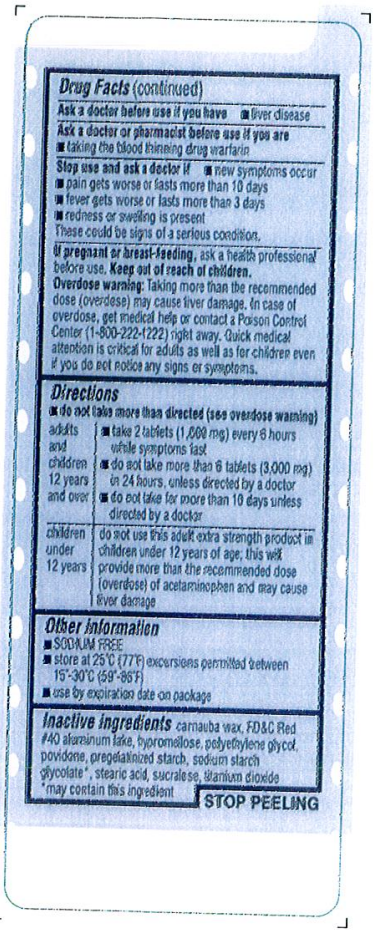
Warnings;

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 (0verdose) 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



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