

ASPIRIN LOW DOSE ENTERIC COATED- aspirin tablet, coated
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.

387R ASA

Active Ingredient in Each tablet

Aspirin 81 mg (NSAID) Non-steroidal anti-inflammatory drug

Ask a doctor before use if: stomach bleeding warning applies to you, you have a history of stomach problems, such as heartburn, you have high blood pressure, heart disease, liver cirrhosis, or kidney disease; you are taking a diuretic, you have asthma, you have not been drinking fluids, you have lost a lot of fluid due to vomiting or diarrhea

Uses: temporarily relieves minor aches and pains: for other uses, see your doctor, but do not use for more than 10 days without consulting your doctor because serious side effects may occur.

Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness

Allergy alert: Aspirin may cause a severe allergic reaction which may include: hives, facial swelling, shock, asthma(wheezing

Stomach bleeding warning: This product contains an NSAID which may cause severe stomach bleeding. The chance is higher if you: are age 60 or older, have had stomach ulcers or bleeding problems, take a blood thinning (anticoagulant) or steroid drug, take other drugs containing prescription or non prescription NSAIDs (aspirin, ibuprofen, naproxen, or others), have 3 or more alcoholic drinks every day while using this product, take more or for a longer time than directed.

Ask a doctor or pharmacist before use if you are taking a prescription drug for diabetes, gout, or arthritis; under a doctor's care for any serious condition; taking any other drug

Do not use if you are allergic to aspirin or any other pain reliever/fever reducer

Stop use and ask a doctor if: you experience any of the following signs of stomach bleeding: feel faint, have bloody or black stools, vomit blood, have stomach pain that does not get better, pain gets worse or lasts more than 10 days, fever gets worse or lasts more than 3 days, redness or swelling is present in the painful area, any new symptoms appear

If pregnant or breast-feeding, ask a health profession before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of the reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions: drink a full glass of water with each dose; adults and children 12 years and over: take 4 to 8 tablets every 4 hours not to exceed 48 tablets in 24 hours unless directed by a doctor
 Children under 12 years - consult a doctor

Inactive ingredients: anhydrous lactose, carnauba wax, colloidal silicon dioxide, croscarmellose sodium, D-C yellow #10 aluminum lake, iron oxide ochre, methacrylic acid copolymer, microcrystalline cellulose, Polysorbate 80, simethicone, sodium hydroxide, sodium lauryl sulfate, talc, titanium dioxide

Uses - temporarily relieves minor aches and pains for other uses, see your doctor, but do not use for more than 10 days without consulting your doctor because serious side effects may occur

Time-Cap Labs, Inc. NDC 49483-387-10
 **Compare to the active ingredient in Bayer® Low Dose

LOW DOSE ASPIRIN REGIMEN
ASPIRIN
ENTERIC
 Safety Coated

Pain Reliever (NSAID)
 SEE NEW WARNINGS INFORMATION

81mg

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN

1000 ENTERIC COATED TABLETS New Improved Formula

Drug Facts
Active ingredient (in each tablet) Purpose
 Aspirin 81 mg (NSAID) Pain reliever
 Nonsteroidal anti-inflammatory drug

Uses temporarily relieves minor aches and pains
 for other uses, see your doctor, but do not use for more than 10 days without consulting your doctor because serious side effects may occur

Warnings
Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.
Allergy alert: Aspirin may cause a severe allergic reaction, which may include: hives facial swelling shock asthma (wheezing)
Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you: are age 60 or older have had stomach ulcers or bleeding problems take a blood thinning (anticoagulant) or steroid drug take other drugs containing prescription or nonprescription NSAIDs

Drug Facts (continued)
 (aspirin, ibuprofen, naproxen, or others) have 3 or more alcoholic drinks every day while using this product take more or for a longer time than directed
Do not use if you are allergic to aspirin or any other pain reliever/fever reducer
Ask a doctor before use if stomach bleeding warning applies to you you have a history of stomach problems, such as heartburn you have high blood pressure, heart disease, liver cirrhosis, or kidney disease you are taking a diuretic you have asthma you have not been drinking fluids you have lost a lot of fluid due to vomiting or diarrhea
Ask a doctor or pharmacist before use if you are
 taking a prescription drug for diabetes, gout, or arthritis under a doctor's care for any serious condition taking any other drug
Stop use and ask a doctor if you experience any of the following signs of stomach bleeding: feel faint have bloody or black stools vomit blood pain gets worse or lasts more than 10 days fever gets worse or lasts more than 3 days redness or swelling is present in the painful area any new symptoms appear

Drug Facts (continued)
 ringing in the ears or a loss of hearing occurs
If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.
Directions drink a full glass of water with each dose adults and children 12 years and over: take 4 to 8 tablets every 4 hours not to exceed 48 tablets in 24 hours unless directed by a doctor children under 12 years: consult a doctor
Other information
 store at 25°C (77°F) excursions permitted between 15°-30°C (59°-86°F) use by expiration date on package
Inactive ingredients anhydrous lactose, carnauba wax, colloidal silicon dioxide, croscarmellose sodium, D&C yellow #10 aluminum lake, iron oxide ochre, methacrylic acid copolymer, microcrystalline cellulose, polysorbate 80, simethicone, sodium hydroxide, sodium lauryl sulfate, talc, titanium dioxide, triethyl citrate
 **This product is not manufactured or distributed by Bayer HealthCare LLC, owner of the registered trademark Bayer® Low Dose. 387R 0510

Manufactured by: Time-Cap Labs, Inc.
 7 Michale Avenue, Farmingdale, NY 11735

WARNING: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS SCUFFED, DOWN, BROKEN OR MISSING

387R 0510
 LOT #:
 EXP. DATE:

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ASPIRIN LOW DOSE ENTERIC COATED			
aspirin tablet, coated			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49483-387
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)		ASPIRIN	81 mg
Inactive Ingredients			
Ingredient Name			Strength
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)			
CARNAUBA WAX (UNII: R12CBM0EIZ)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)			
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)			

IRON (UNII: E1UOL152H7)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics

Color	yellow	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	embossed;upper;heart;lower;plain
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49483-387-12	120 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/17/2018	
2	NDC:49483-387-10	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/17/2018	
3	NDC:49483-387-00	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 final	part343	06/28/2010	

Labeler - Time-Cap Labs, Inc (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
Time-Cap Labs, Inc		037052099	manufacture(49483-387)