

ASPIRIN LOW DOSE ENTERIC COATED- aspirin 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.

49483-390 ASA 81 MG

Active ingredient (in each tablet)

Aspirin 81 mg (NSAID*).Pain reliever

*nonsteroidal anti-inflammatory drug

anhydrous lactose, carnauba wax, colloidal silicon dioxide, croscarmellose sodium, d&c yellow#10 aluminum lake, iron oxide ochre, methacrylic acid and ethyl acrylate copolymer, microcrystalline cellulose, Polysorbate 80, simethicone, sodium hydroxide, sodium lauryl sulfate, talc, titanium dioxide, triethyl citrate

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

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

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
-

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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.

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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

have 3 or more alcoholic drinks every day while using this product

take more or for a longer time than directed

take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)

390R BULK

PRODUCT #

P.O. #

TIME-CAP LABS, INC.
7 MICHAEL AVENUE, FARMINGDALE, N.Y. 11735\

631 · 753 · 9090 .

CODE # 390R

PRODUCT : 81MG ASPIRIN E/C YELLOW TABLETS

(RAISED A)

**EACH TABLET CONTAINS:
ASPIRIN 81 MG**

TAMPER · EVIDENT FEATURE:

For retail sale, OTC human drug products (tablets in this package) should be packaged with a minimum of one tamper-evident feature and the respective package label should identify all tamper-evident features(s) and should be displayed in a most prominent place so that it will be unaffected if the tamper-evident feature(s) of the package is breached or missing.

CONTROL #

**APPROXIMATE
QUANTITY OF CTNS.**

CAUTION: FOR MANUFACTURING, PROCESSING, OR REPACKING

**STORE At CONTROLLED ROOM TEMPERATURE 15° – 30 °C (59° – 86° F)
IN ORIGINAL TIGHTLY CLOSED BULK CONTAINERS.**

Repackage Immediately Upon Receipt

SHIP TO:

**KEEP TIGHTLY CLOSED IN A DRY PLACE, DO NOT EXPOSE TO EXCESSIVE HEAT.
WARNING: KEEP OUT OF THE REACH OF CHILDREN. THIS IS A BULK SHIPMENT
INTENEDE FOR FURTHUR PROCESSING ONLY, CONTENTS SHOULD BE APPROVED,
REPACKAGED IMMEDIATELY AND LABELED IN STRICT CONFORMANCE WITH THE
PERTINENT FD&C ACT AND REGULATIONS THEREUNDER,**

Enter section text here

ASPIRIN LOW DOSE ENTERIC COATED

aspirin tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49483-390
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)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)	
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;A;lower;plain
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49483-390-00	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	07/16/2010	

Labeler - Time-Cap Labs, Inc (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
Time-Cap Labs, Inc		037052099	manufacture(49483-390)

Revised: 12/2018

Time-Cap Labs, Inc