ASPIRIN LOW DOSE ENTERIC COATED- as pirin 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

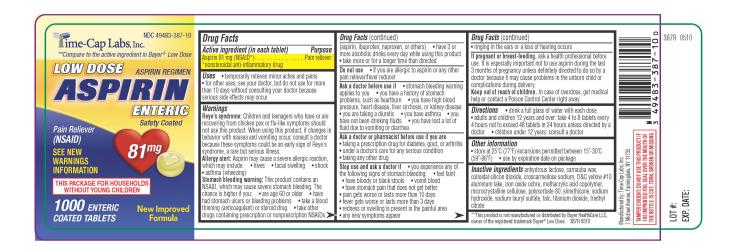
If pregnant or breast-feeding, ask a health profession before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

eep 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



Enter section text here

ASPIRIN LOW DOSE ENTERIC COATED aspirin tablet, coated **Product Information** Product Type HUMAN OTC DRUG NDC:49483-387 Item Code (Source) **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		
ANHYDRO US LACTO SE (UNII: 3S Y5LH9 PMK)			
CARNAUBA WAX (UNII: R12CBM0EIZ)			
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)			
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)			
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)			

IRON (UNII: E1UOL152H7)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SO DIUM HYDRO XIDE (UNII: 55X04QC32I)	
SODIUM LAURYL SULFATE (UNII: 368 GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics			
Color	ye llo w	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	embossed;upper;heart;lower;plain
Contains			

F	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)	

Revised: 12/2018 Time-Cap Labs, Inc