

ASPIRIN- aspirin tablet
America Medic & Science

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.

Aspirin 81 mg Low Dose
Safety Coated Aspirin

Drug Facts

Active ingredient (in each tablet)

Aspirin, 81 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever

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

- facial swelling
- asthma (wheezing)
- shock
- hives

Stomach bleeding warning: This product contains a nonsteroidal anti-inflammatory drug (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

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
- taking any other drug
- under a doctor's care for any serious condition

Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away.
- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
 - have stomach pain that does not get better
 - pain gets worse or lasts more than 10 days
 - redness or swelling is present
 - fever gets worse or lasts more than 3 days
 - new symptoms occur
 - ringing in the ear or 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.

Do not use this product if printed safety seal under cap is torn or missing.

Aspirin is not appropriate for everyone, so be sure to talk to your doctor before you begin an aspirin regimen.

Directions

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

anhydrous lactose, carnauba wax, iron oxide ochre, polysorbate 80, simethicone, sodium hydroxide, sodium lauryl sulfate, starch

Questions or comments?

call 1-855-314-1850

NDC 49638-481-36



ASPIRIN aspirin tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49638-481
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		
STARCH, CORN (UNII: O8232NY3SJ)				
SODIUM LAURYL SULFATE (UNII: 368GB5141J)				
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)				
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
SODIUM HYDROXIDE (UNII: 55X04QC32I)				
CARNAUBA WAX (UNII: R12CBM0EIZ)				
BROWN IRON OXIDE (UNII: 1N032N7MFO)				
DIMETHICONE (UNII: 92RU3N3Y1O)				
Product Characteristics				
Color	yellow	Score	no score	
Shape	ROUND	Size	8mm	
Flavor		Imprint Code	AP;121	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49638-481-36	365 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/18/2017	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part343	01/18/2017		

Labeler - America Medic & Science (071065464)

Establishment

Name	Address	ID/FEI	Business Operations
TIME CAP LABORATORIES, INC		037052099	manufacture(49638-481)

Revised: 1/2017

America Medic & Science