LOW DOSE ASPIRIN- aspirin 81 mg delayed release tablets tablet WALGREENS

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.

481R Walgreens 0363-0686 Aspirin 81 mg Tablets 500 ct

DRUG FACTS

Active ingredient (in each tablet)

Aspirin 81 mg (NSAID*)
*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever

Uses

- for the temporary relief of minor aches and pains or as recommended by your doctor. Because of its delayed action, this product will not provide fast relief of headaches or other symptoms needing immediate relief.
- ask your doctor about other uses for enteric-coated 81 mg Aspirin

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 problem
- take a blood thinning (anticoagulant) or steroid drug
- take other drug containing prescription or nonprescription 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
- if you have ever had an allergic reaction to this product or any of its ingredients

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

Ask a doctor or pharmacist before use if you are taking a prescription drug for

- gout
- diabetes
- arthritis

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
- 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

new symptoms occur

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 (1-800-222-1222) right away.

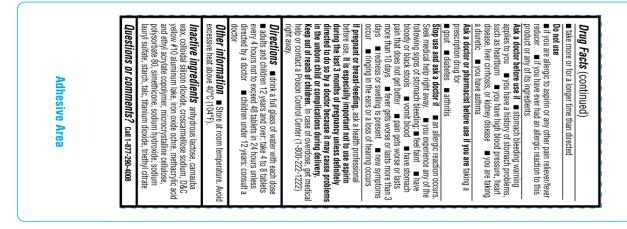
Directions

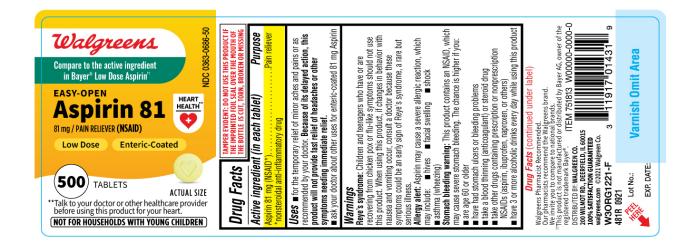
- drink a full glass of water with each dose
- adults and children 12 years and over: take 4 to 8 tablets every 4 hours not to exceed 48 tablets in 24 hours unless directed by a doctor
- children under 12 years: consult a doctor

Other information

• Store at room temprature. Avoid excessive heat above 40°C (104°F).

Inactive ingredients 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, starch, talc, titanium dioxide, triethyl citrate.





LOW DOSE ASPIRIN

aspirin 81 mg delayed release tablets tablet

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-0686	
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

SODIUM HYDROXIDE (UNII: 55X04QC32I)

SODIUM LAURYL SULFATE (UNII: 368GB5141J)

STARCH, CORN (UNII: 08232NY3SJ)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

MICROCRYSTALLINE CELLULOSE (UNII: 0P1R32D61U)

POLYSORBATE 80 (UNII: 6OZP39ZG8H)

SILICON DIOXIDE (UNII: ETJ7Z 6XBU4)

CROSCARMELLOSE SODIUM (UNII: M280L1HH48)

METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)

FERRIC OXIDE RED (UNII: 1K09F3G675)

CARNAUBA WAX (UNII: R12CBM0EIZ)

D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)

TALC (UNII: 7SEV7J4R1U)

TRIETHYL CITRATE (UNII: 8Z96QXD6UM)

ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)

Product Characteristics					
Color	yellow	Score	no score		
Shape	ROUND	Size	7mm		
Flavor		Imprint Code	HEART		
Contains					

l	Packaging				
	# Item Code Package Description		Marketing Start Date	Marketing End Date	
		NDC:0363-0686- 50	500 in 1 BOTTLE; Type 0: Not a Combination Product	10/08/2021	

Marketing Information			
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date
OTC monograph not final	part343	10/08/2021	

Labeler - WALGREENS (008965063)

Registrant - TIME CAP LABORATORIES, INC. (037052099)

Establishment				
Name	Address	ID/FEI	Business Operations	
TIME CAP LABORATORIES, INC.		037052099	manufacture(0363-0686)	

Revised: 12/2021 WALGREENS