

## **LOW DOSE ASPIRIN- aspirin tablet, delayed release BJWC (Berkley & Jensen / BJ's)**

-----

### **BJs Low Dose Aspirin 81 mg Tablets**

#### ***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
- asthma (wheezing)
- shock

**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 (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
  - vomit blood
  - have bloody or black stools
  - 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 right away (1-800-222-1222).

***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
- 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

***Questions or comments?*** Call **1-877-290-4008**

481R 365ct Label



aspirin tablet, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68391-481
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
<b>ASPIRIN</b> (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	81 mg

Inactive Ingredients	
Ingredient Name	Strength
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>DIMETHICONE, UNSPECIFIED</b> (UNII: 92RU3N3Y1O)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>D&amp;C YELLOW NO. 10 ALUMINUM LAKE</b> (UNII: CQ3XH3DET6)	
<b>METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER</b> (UNII: NX76LV5T8J)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>ANHYDROUS LACTOSE</b> (UNII: 3SY5LH9PMK)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TRIETHYL CITRATE</b> (UNII: 8Z96QXD6UM)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	

Product Characteristics			
<b>Color</b>	yellow	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	7mm
<b>Flavor</b>		<b>Imprint Code</b>	Heart
<b>Contains</b>			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68391-481-93	2 in 1 CARTON	08/25/2025	
1	NDC:68391-481-65	365 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	08/25/2025	

**Labeler** - BJWC (Berkley & Jensen / BJ's) (159082692)

**Registrant** - TIME CAP LABORATORIES, INC (037052099)

**Establishment**

Name	Address	ID/FEI	Business Operations
Time Cap Laboratories, Inc.		037052099	manufacture(68391-481)

Revised: 8/2025

BJWC (Berkley & Jensen / BJ's)