# LOW DOSE ASPIRIN 81MG- aspirin tablet BETTER LIVING BRANDS LLC.

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.

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## 481R\_Albertson\_21130-481\_Aspirin 81mg EC Yellow

## **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:
- 1. feel faint
- 2. vomit blood
- 3. have bloody or black stools
- 4. 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**

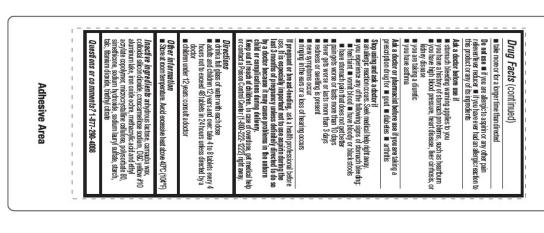
- drink a full glass of water with each dose
- adults and children 12 years and over: take 4 to 8 tablets every 4 hours not to exceed 48 tablets in 24 hours unless directed by a doctor
- children under 12 years: consult a doctor

#### Other information

• store at room temperature. 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? 1-877-290-4008

















#### **LOW DOSE ASPIRIN 81MG**

aspirin tablet

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:21130-481

Route of Administration ORAL

## **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	81 ma

Inactive Ingredients			
Ingredient Name	Strength		
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)			
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)			
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			

SODIUM HYDROXIDE (UNII: 55X04QC32I)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POLYSORBATE 80 (UNII: 60ZP39ZG8H)	
DIMETHICONE (UNII: 92RU3N3Y10)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
FERRIC OXIDE YELLOW (UNII: EX43802MRT)	

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

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-481- 32	1 in 1 CARTON	07/14/2023	
1		32 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:21130-481- 12	1 in 1 CARTON	07/14/2023	
2		120 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:21130-481- 20	1 in 1 CARTON	07/14/2023	
3		200 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:21130-481- 50	500 in 1 BOTTLE; Type 0: Not a Combination Product	07/14/2023	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	07/14/2023	

## **Labeler - BETTER LIVING BRANDS LLC. (009137209)**

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
TIME CAP LABORATORIES, INC.		037052099	manufacture(21130-481)	

Revised: 8/2023 BETTER LIVING BRANDS LLC.