

## **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.*

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### **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 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? Call 1-877-290-4008

**Drug Facts (continued)**

- 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
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- 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**
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    - fever gets worse or lasts more than 3 days
    - redness or swelling is present
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  - drink a full glass of water with each dose
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- Other information**
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- Inactive ingredients** anhydrous lactose, cantharidin, yellow #10 aluminum lake, croscarmellose sodium, D&C and ethyl acrylate copolymer, microcrystalline cellulose, polyethylene glycol, simethicone, sodium hydroxide, sodium lauryl sulfate, starch, talc, titanium dioxide, triethyl citrate

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

**Adhesive Area**



Compare to the active ingredient in Bayer® Low Dose Aspirin™

**EASY-OPEN Aspirin 81**  
81 mg / PAIN RELIEVER (NSAID)

Low Dose    Enteric-Coated

**500** TABLETS

ACTUAL SIZE

\*\*Talk to your doctor or other healthcare provider before using this product for your heart.

**NOT FOR HOUSEHOLDS WITH YOUNG CHILDREN**

**Drug Facts**

**Active ingredient (in each tablet)** Aspirin 81 mg (NSAID)\*, nonsteroidal anti-inflammatory drug

**Purpose** Pain reliever

**Uses**

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- have 3 or more alcoholic drinks every day while using this product

**Drug Facts (continued under label)**

Walgreens Pharmacist Recommended. Our pharmacists recommend the Walgreens brand. This product is not manufactured or distributed by Bayer AG, owner of the registered trademark Bayer.

ITEM 751813 W000000-0000-0

DISTRIBUTED BY: WALGREEN CO.  
200 WILMOT RD., DEERFIELD, IL 60015

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W3ORG1221-F  
481R 0921

Lot No.:  
**PEEL HERE** →

EXP. DATE:

**Varnish Omit Area**

## 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

<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)
<b>METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER</b> (UNII: NX76LV5T8J)
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)
<b>D&amp;C YELLOW NO. 10 ALUMINUM LAKE</b> (UNII: CQ3XH3DET6)
<b>TALC</b> (UNII: 7SEV7J4R1U)
<b>TRIETHYL CITRATE</b> (UNII: 8Z96QXD6UM)
<b>ANHYDROUS LACTOSE</b> (UNII: 3SY5LH9PMK)

### 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:0363-0686-50	500 in 1 BOTTLE; Type 0: Not a Combination Product	10/08/2021	

### Marketing Information

Marketing Category	Application Number or Monograph 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)