

## **LOW DOSE ASPIRIN- aspirin tablet, coated**

### **Akron Phama**

*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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## **Aspirin**

### **Low Dose**

### **Drug Facts**

#### **Active Ingredient (in each tablet)**

**Aspirin 81 mg (NSAID)\***

**\* nonsteroidal anti-inflammatory drug**

**Purpose Pain reliever**

#### **Uses**

- temporarily relief of minor aches and pains or as recommended by your doctor.

**Because of its delayed release action, this product will not provide fast relieve of headache or symptoms needing immediate relief.**

#### **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 the 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
- shock
- facial swelling
- asthma (wheezing)

**Stomach bleeding warning:** This product contains an NSAID, which may cause severe stomach bleeding. This 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 of 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

#### **Ask a doctor before use if**

- you have asthma
- 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

**Ask a doctor or pharmacist before use if you are**

- taking a prescription drug for diabetes, gout, or arthritis
- under a doctor's care for any serious condition
- taking any other drug

**Stop use and ask a doctor if**

- 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
- an allergic reaction occurs. Seek medical help right away.
- ringing in the ears or loss of hearing occurs
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days
- redness or swelling present in the painful area
- new symptoms occur.

These could be signs of a serious condition.

**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. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

**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 while symptoms last
- do not take more than 48 tablets in 24 hours unless directed by a doctor
- **children under 12 years:** ask a doctor

**Other information**

- store at room temperature 15 °-30 °C(59 °-86 °F)
- read all product information before using

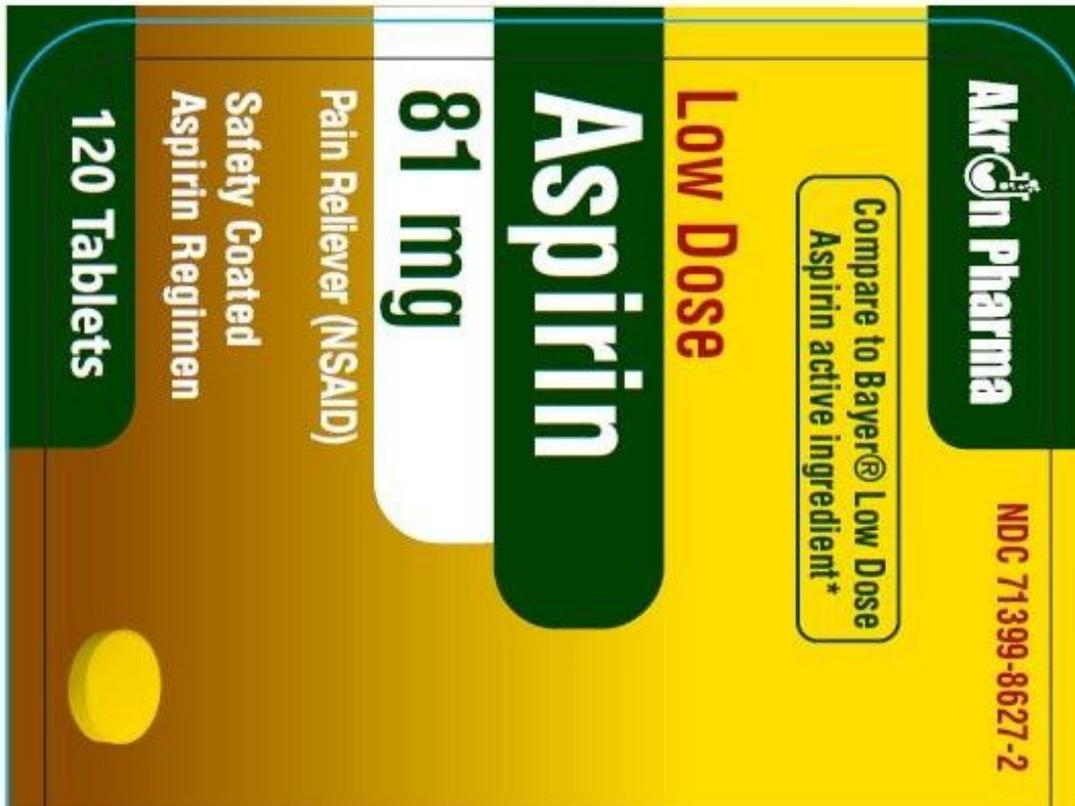
**Inactive ingredients**

anhydrous lactose, carnauba wax, colloidal silicon dioxide, croscarmellose sodium, FD&C yellow#10 al lake, FD&C yellow#6 al lake, iron oxide ochre, methacrylic acid copolymer,

microcrystalline cellulose, polysorbate 80, simethicone, sodium hydroxide, sodium lauryl sulfate, talc, titanium dioxide, triethyl citrate

**Questions or comments?** Call toll-free 1-877-225-6999

Monday to Friday 9AM to 5PM



The image shows the front of a yellow and green box for Aspirin 81 mg Low Dose. The box features the Akorn Pharma logo in the top right corner. The text on the box includes: "Compare to Bayer® Low Dose Aspirin active ingredient\*", "Low Dose", "Aspirin", "81 mg", "Pain Reliever (NSAID)", "Safety Coated Aspirin Regimen", and "120 Tablets". The NDC number 71399-8627-2 is printed vertically on the right side.

## Drug Facts

| <i>Active ingredient (in each tablet)</i> | <i>Purpose</i> |
|---|----------------|
| Aspirin 81 mg (NSAID)* .....              | Pain reliever  |
| * nonsteroidal anti-inflammatory drug     |                |

### Uses

■ temporarily relief of minor aches and pains or as recommended by your doctor. **Because of its delayed release action, this product will not provide fast relief of headache or symptoms needing immediate relief.**

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**Do not use** ■ if you are allergic to aspirin, or any other pain reliever/fever reducer

**DRUG FACTS CONTINUED** on back of the label 

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL  
UNDER CAP IS BROKEN OR MISSING**

**\*This product is not manufactured or distributed by Bayer HealthCare LLC.,  
owner of the registered trademark Bayer® Low Dose Aspirin.**

PEEL HERE 

**Akron Pharma**

Manufactured for:  
Akron Pharma, Inc.  
Fairfield, NJ-07004  
www.akronpharma.com  
Made in USA   
Rev.:12/20



### ***Drug Facts (Continued)***

#### **Ask a doctor before use if**

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- stomach bleeding warning applies to you
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Seek medical help right away.

■ ringing in the ears or loss of hearing occurs

■ pain gets worse or lasts for more than 10 days

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### ***Other information***

■ store at room temperature 15°-30°C (59°-86°F)

■ read all product information before using

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### ***Inactive ingredients***

anhydrous lactose, carnauba wax, colloidal silicon dioxide, croscarmellose sodium, FD&C yellow#10 al lake, FD&C yellow#6 al lake, iron oxide ochre, methacrylic acid copolymer, microcrystalline cellulose, polysorbate 80, simethicone, sodium hydroxide, sodium lauryl sulfate, talc, titanium dioxide, triethyl citrate

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Monday to Friday 9AM to 5PM

# LOW DOSE ASPIRIN

aspirin tablet, coated

## Product Information

|                                |                |                           |                |
|--------------------------------|----------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:71399-8627 |
| <b>Route of Administration</b> | 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>ANHYDROUS LACTOSE</b> (UNII: 3SY5LH9PMK)  |          |
| <b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)   |          |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)  |          |
| <b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)                                     |          |
| <b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)                                    |          |
| <b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)                                    |          |
| <b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)   |          |
| <b>METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (4500 MPA.S)</b> (UNII: T967IEU43C) |          |
| <b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)                               |          |
| <b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)   |          |
| <b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)  |          |
| <b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)   |          |
| <b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)                                    |          |
| <b>TALC</b> (UNII: 7SEV7J4R1U)   |          |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)   |          |
| <b>TRIETHYL CITRATE</b> (UNII: 8Z96QXD6UM)   |          |

## Product Characteristics

|                 |        |                     |          |
|-----------------|--------|---------------------|----------|
| <b>Color</b>    | yellow | <b>Score</b>        | no score |
| <b>Shape</b>    | ROUND  | <b>Size</b>         | 6mm      |
| <b>Flavor</b>   |        | <b>Imprint Code</b> | A1       |
| <b>Contains</b> |        |                     |          |

## Packaging

| # | Item Code        | Package Description                                 | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:71399-8627-1 | 1000 in 1 BOTTLE; Type 0: Not a Combination Product | 05/12/2021           |                    |
| 2 | NDC:71399-       | 120 in 1 BOTTLE; Type 0: Not a Combination          | 05/12/2021           |                    |

8627-2

Product

05/12/2021

## Marketing Information

| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part343                                  | 05/12/2021           |                    |

**Labeler -** Akron Phama (067878881)

Revised: 2/2023

Akron Phama