

**ASPIRIN- aspirin tablet, delayed release**  
**SPIRIT PHARMACEUTICALS LLC**

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**LOW DOSE ASPIRIN**

***Drug Facts***

**Active ingredient (in each tablet)**

Aspirin 81 mg (NSAID) <sup>1</sup>

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<sup>1</sup> 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, fever or other symptoms needing immediate relief.**
- ask your doctor about other uses for Aspirin 81 mg

**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 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

### **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 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
  - 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.

### **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

## Inactive ingredients

acrycoat, colloidal silicon dioxide, croscarmellose sodium, D&C yellow #10, lactose, microcrystalline cellulose, polysorbate 80, sodium hydroxide, talc, titanium dioxide, triethyl citrate, yellow oxide of iron

## Questions or comments?

1-888-333-9792

## PRINCIPAL DISPLAY PANEL

Low Dose

Aspirin

Aspirin (NSAID) 81 mg - Pain Reliever

40 Coated Tablets

**VALUHEALTH**  
— BY SPIRIT —

Low Dose  
**aspirin**  
Aspirin (NSAID) 81 mg  
Pain Reliever

40 coated tablets

**DO NOT USE IF SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

**READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION**

**Active ingredient (in each tablet)** Purpose  
Aspirin 81 mg (NSAID)\* ..... Pain reliever  
\*nonsteroidal anti-inflammatory drug

**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 Aspirin 81 mg

**Warnings**  
**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

**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).

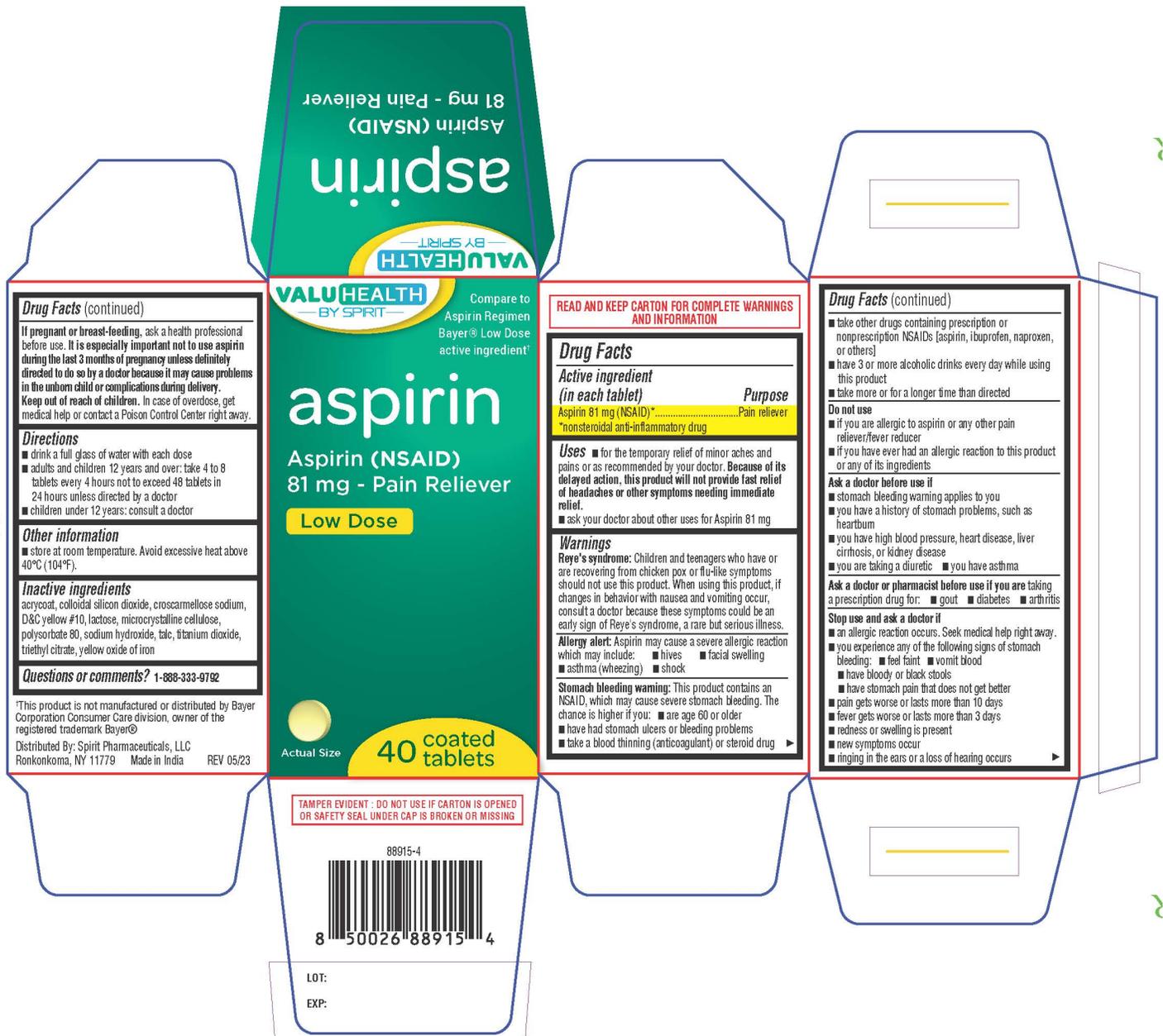
**Questions or comments?** Call 1-888-333-9792

Distributed By: Spirit Pharmaceuticals, LLC  
Ronkonkoma, NY 11779  
REV 05/23

88915-4

LOT: \_\_\_\_\_  
EXP: \_\_\_\_\_

Made in India



## ASPIRIN

aspirin tablet, delayed release

### Product Information

|                                |                |                           |                |
|--------------------------------|----------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:68210-4128 |
| <b>Route of Administration</b> | 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>METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1)</b> (UNII: 74G4R6TH13) |          |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)                                        |          |
| <b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)                                   |          |
| <b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)                                  |          |
| <b>LACTOSE, UNSPECIFIED FORM</b> (UNII: J2B2A4N98G)                              |          |
| <b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)                            |          |
| <b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)                                         |          |
| <b>WATER</b> (UNII: 059QF0KO0R)                                                  |          |
| <b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)                                       |          |
| <b>TALC</b> (UNII: 7SEV7J4R1U)                                                   |          |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)                                       |          |
| <b>TRIETHYL CITRATE</b> (UNII: 8Z96QXD6UM)                                       |          |
| <b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)                                    |          |

### Product Characteristics

|                 |        |                     |          |
|-----------------|--------|---------------------|----------|
| <b>Color</b>    | yellow | <b>Score</b>        | no score |
| <b>Shape</b>    | ROUND  | <b>Size</b>         | 8mm      |
| <b>Flavor</b>   |        | <b>Imprint Code</b> | 81       |
| <b>Contains</b> |        |                     |          |

### Packaging

| # | Item Code        | Package Description                               | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------------------------------------|----------------------|--------------------|
| 1 | NDC:68210-4128-4 | 1 in 1 CARTON                                     | 04/27/2021           |                    |
| 1 |                  | 40 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                                     | 04/27/2021           |                    |

**Labeler** - SPIRIT PHARMACEUTICALS LLC (179621011)

Revised: 12/2024

SPIRIT PHARMACEUTICALS LLC