## 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>

1 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?

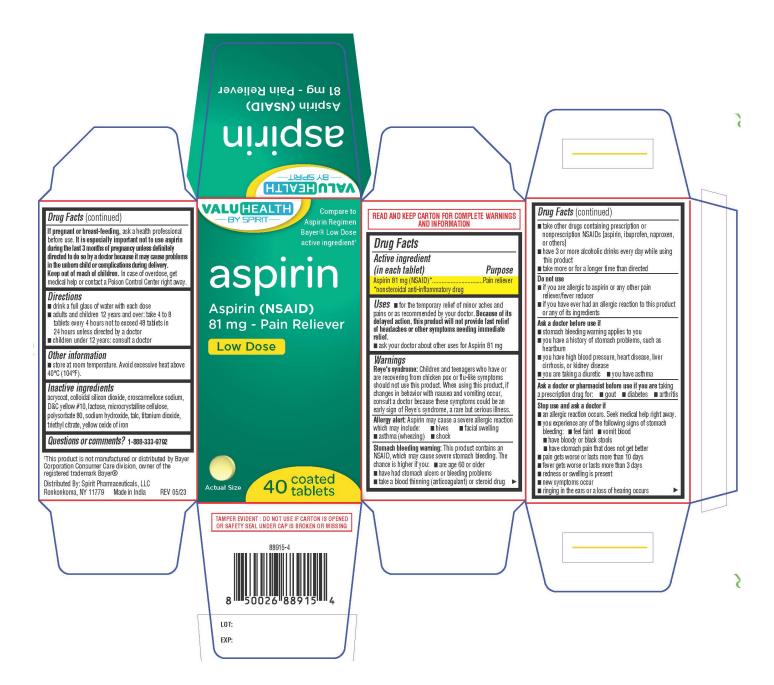
1-888-333-9792

#### PRINCIPAL DISPLAY PANEL

Low Dose Aspirin Aspirin (NSAID) 81 mg - Pain Reliever

## 40 Coated Tablets





#### **ASPIRIN**

aspirin tablet, delayed release

# Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:68210-4128 Route of Administration ORAL

# Active Ingredient/Active Moiety Ingredient Name Basis of Strength ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E) ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)

### **Inactive Ingredients**

Ingredient Name	Strength
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYSORBATE 80 (UNII: 60ZP39ZG8H)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
FERRIC OXIDE YELLOW (UNII: EX43802MRT)	

Product Characteristics					
Color	yellow	Score	no score		
Shape	ROUND	Size	8mm		
Flavor		Imprint Code	81		
Contains					

P	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: 12/2023 SPIRIT PHARMACEUTICALS LLC