

**ASPIRIN- aspirin tablet, delayed release**  
**AAA Pharmaceutical, Inc.**

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**RES-1080B-2019-0911**

***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 this product

**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

**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:

- diabetes
- gout
- 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
  - vomit blood
  - have bloody or black stools
  - have stomach pain that does not get better
- pain gets worse or lasts for more than 10 days
- redness or swelling is present
- new symptoms occur
- ringing in the ears or loss of hearing occurs

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 right away (1-800-222-1222).

**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 between 20°-25°C (68°-77°F) in a dry place
- retain carton for complete product information and warnings

### **Inactive ingredients**

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

### **PRINCIPAL DISPLAY PANEL**

#### ***RESTORE u***

NDC 57344-080-01

†COMPARE TO THE ACTIVE INGREDIENT IN BAYER® LOW DOSE ASPIRIN

LOW DOSE

Aspirin

Pain Reliever  
(NSAID)

Safety Coated

81mg

120 ENTERIC COATED TABLETS - 81 MG EACH



## Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
BROWN IRON OXIDE (UNII: 1N032N7MFO)	
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	

## 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:57344-080-01	1 in 1 CARTON	07/01/2017	
1		120 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:57344-080-20	300 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/15/2024	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	07/01/2017	

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**Labeler** - AAA Pharmaceutical, Inc. (181192162)

Revised: 6/2024

AAA Pharmaceutical, Inc.