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

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



Because of its delayed action, this product will not provide fast relief of headaches or

reaction which may include:

right away.

- shock facial swelling
- Stomach bleeding warning: This product contains an NSAID, which may cause severe asthma (wheezing) stomach bleeding. are age 60 or older The chance is higher if you:

take a blood thinning (anticoagulant) or

ringing in the ears or loss of hearing occurs

These could be signs of a serious condition.

new symptoms occur redness or swelling is present

681 Main Street Lumberton, NJ 08048

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AAA Pharmaceutical, Inc Distributed by:

Petrop Metrop

Ogin Reliever

Msbirin

have had stomach ulcers or bleeding problems

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Reye's syndrome: Children and teenagers who Warnings

ask your doctor about other uses for this product other symptoms needing immediate relief.

for the temporary relief of minor aches and Uses pains or as recommended by your doctor

you have a history of stomach problems, such as Ask a doctor before use if pain reliever/fever reducer stomach bleeding warning applies to you

you have high blood pressure, heart disease liver cirrhosis, or kidney disease

 you are taking a diuretic taking a prescription drug for: Ask a doctor or pharmacist before use if you are you have asthma

 an allergic reaction occurs. Seek medical help Stop use and ask a doctor if diabetes gout arthritis

retain carton for complete product information

and warnings

 have bloody or black stools
 vomit blood
 have stomach pain that does not get better
 pain gets worse or lasts for more than 10 days you experience any of the following signs of stomach bleeding:
feel faint

anhydrous lactose, carnauba wax, colloidal silicon dioxide, croscarmellose sodium, D&C yellow #10

colloidal silicor

RESTORE

inactive ingredients

sulfate, starch, talc, titanium dioxide, triethyl citrate copolymer, microcrystalline cellulose, polysorbate aluminum lake, iron oxide ochre, methacrylic acid

simethicone, sodium hydroxide, sodium lauryl

EXPIRATION STAMPING This product is not manufactured or distributed by Bayer HealthCare LLC, distributor of Bayer® Low Dose Aspirin. FOR LOT AND INK AND COATING FREE DO NOT USE IF IMPRINTED SEAL UNDER CAP IS BROKEN OR MISSIN 1089 F1080B01RES_R0 ∞ 11995

Drug Facts (continued)

 have 3 or more alcoholic drinks every day take other drugs containing prescription or naproxen, or others) nonprescription NSAIDs (aspirin, ibuprofen, while using this product

Pain reliever Purpose

Do not use if you are allergic to aspirin or any other take more or for a longer time than directed

Directions

 children under 12 years: consult a doctor store between 20°-25°C (68°-77°F) in a dry place Other information in 24 hours unless directed by a doctor

unborn child or complications during delivery.

Keep out of reach of children. In case of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the Control Center right away (1-800-222-1222) overdose, get medical help or contact a Poison

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

professional before use. It is especially important not to use aspirin during the last 3 months of

If pregnant or breast-feeding, ask a health Drug Facts (continued)



Safety Coated 120 ENTERIC COATED TABLETS - 81 MG EACH

ASPIRIN

aspirin tablet, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57344-080
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
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE 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: 60ZP39ZG8H)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: 08232NY3SJ)	
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	

Labeler - AAA Pharmaceutical, Inc. (181192162)

Revised: 6/2024 AAA Pharmaceutical, Inc.