

ASPIRIN- aspirin tablet, delayed release
SPIRIT PHARMACEUTICALS LLC

ASPIRIN

Drug Facts

Active ingredient (in each tablet)

Aspirin 81mg (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, 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

- **each tablet contains:** sodium 0.36 mg
- 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**

Compare to the active ingredient in Bayer® Low Dose Aspirin Regimen**

ASPIRIN

ADULT LOW STRENGTH

PAIN RELIEVER

ASPIRIN 81 mg (NSAID)*

120 TABLETS

ENTERIC SAFETY COATED

EXP: _____
 LOT: _____
 0 402321 0559 8
 8-65008

TAMER'S EVIDENCE: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

VALUMEDS
 Compare to the active ingredient in Bayer®
 Low Dose Aspirin Regimen®
 low dose
ASPIRIN 81 mg
 pain reliever
 (NSAID)

NDC 68210-5100-1

aspirin regimen
120 tablets
 enteric safety coated



Actual Size

Distributed by: Spirit Pharmaceuticals, LLC
 Ronkonkoma, NY 11779 CR15 0718

Made in India

Drug Facts (continued)

- Take other drugs containing prescription or non-prescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- Take 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 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:

- you experience any of the following signs of stomach bleeding:
 - black or tarry stool
 - vomit blood
 - have bloody or black stool
 - have stomach pain that does not get better
 - your stools are dark and more than 10 days
 - swallowing is painful or difficult to swallow
 - new symptoms occur
 - ringing in the ears or a loss of hearing occurs

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, fever or other symptoms needing immediate relief.

Warnings
 Pele's syndrome: Children and teenagers who have or are recovering from chickenpox or the flu 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 Pele'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 thinner (anticoagulant) or steroid drug

Drug Facts (continued)

If pregnant or breast-feeding, ask a health professional to use this use. It is especially important not to use this 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
- at this age: 12 years and over: take 4 to 6 tablets every 4 hours not to exceed 48 tablets in 24 hours unless directed by a doctor
- at this age: under 12 years: ask a doctor

Other information

- each tablet contains sodium 0.35 mg
- some carbon for full directions and warnings
- store at room temperature

Inactive ingredients
 acrylonitrile, colloidal silicon dioxide, croscarmellose sodium, DRC yellow #10, lactose, microcrystalline cellulose, polyacrylate 80, sodium hydroxide, talc, titanium dioxide, triethyl citrate, yellow oxide of iron

Questions or comments? 1-811-333-7112

This product is not manufactured or distributed by Bayer Corporation. Contact your doctor or pharmacist for more information. Bayer is a registered trademark of Bayer Corporation.

ASPIRIN
 aspirin tablet, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-5100
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
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: 6OZP39ZG8H)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-5100-1	1 in 1 CARTON	03/10/2020	
1		120 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	03/10/2020	

Labeler - SPIRIT PHARMACEUTICALS LLC (179621011)