

VALUMEDS ASPIRIN- aspirin tablet, delayed release
SPIRIT PHARMACEUTICALS LLC

VALUMEDS 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**

Distributed By:

Spirit Pharmaceuticals, LLC

Ronkonkoma, NY 11779

PRINCIPAL DISPLAY PANEL - 100 Tablets Bottle

VALUMEDS

ASPIRIN

ADULT LOW STRENGTH

PAIN RELIEVER

ASPIRIN 81 mg

(NSAID)*

100 TABLETS

ENTERIC SAFETY COATED

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

ASPIRIN

ADULT LOW STRENGTH PAIN RELIEVER

ASPIRIN 81 mg (NSAID)*

100 TABLETS
ENTERIC SAFETY COATED

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL BREAKS CAP IS SWOLLEN OR IMPAIRED

Drug Facts

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

Uses
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■ 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, it 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:

(continued under label)

Distributed By: Spirit Pharmaceuticals, LLC
Ronkonkoma, NY 11779 ORIG 04/17

ITEM# 981-01

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Lot No. Exp. Date

FEEL THE DIFFERENCE

MIN. NO COPY

Drug Facts (continued)

■ 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

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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

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Questions or comments? 1-888-333-9792

**This product is not manufactured or distributed by Bayer Corporation Consumer Care Division, owner of the registered trademark Bayer® Low Dose Aspirin Regimen

VALUMEDS ASPIRIN

aspirin tablet, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-0150
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
CROSCARMELOSE 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)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

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:68210-0150-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2017	
2	NDC:68210-0150-5	1 in 1 CARTON	04/11/2018	
2		50 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	05/15/2017	

Labeler - SPIRIT PHARMACEUTICALS LLC (179621011)

Revised: 12/2023

SPIRIT PHARMACEUTICALS LLC