

VALUMEDS ASPIRIN- aspirin tablet, delayed release
SPIRIT PHARMACEUTICALS LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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

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

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
■ 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:

(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

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
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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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
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)	

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 not final	part343	05/15/2017	

Labeler - SPIRIT PHARMACEUTICALS LLC (179621011)

Establishment

Name	Address	ID/FEI	Business Operations
ELYSIUM PHARMACEUTICALS LTD		915664486	manufacture(68210-0150)

Revised: 4/2018

SPIRIT PHARMACEUTICALS LLC