

**VALUMEDS ASPIRIN- aspirin tablet, delayed release**  
**SPIRIT PHARMACEUTICALS LLC**

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**ASPIRIN 325 MG TABLETS**

**Active ingredient (in each tablet)**

Aspirin (NSAID)\* 325 mg

\*nonsteroidal anti-inflammatory drug

**Purpose**

Pain reliever

- temporary relieves minor aches and pains due to:
- headache
- minor arthritis pain
- toothache
- menstrual pain
- colds
- or as recommended by a doctor

**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
- shock
- facial swelling
- asthma (wheezing)

**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 have ever had an allergic reaction 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 or arthritis

**Stop use and ask a doctor if**

- 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 more than 10 days
  - redness or swelling is present
  - any new symptom appear
  - ringing in the ears or a 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**

- adults and children 12 years of age and over: take 1 to 2 tablets every 4 hours, while symptoms persist. Drink a full glass of water with each dose.
- do not take more than 12 tablets in 24 hours unless directed by a doctor
- children under 12 years of age: ask a doctor

**Other information**

- store below 25 °C (77 °F)
- Tamper Evident Feature: Do not use if printed inner-seal beneath cap is missing or broken

corn starch, croscarmellose sodium, D&C yellow #10 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, methacrylic acid copolymer, microcrystalline cellulose, mineral oil, polysorbate 80, simethicone, sodium hydroxide, sodium lauryl sulfate, talc, titanium dioxide, triethyl citrate

**Questions or comments?****1(888)333-9792****VALUMEDS™**

Compare to the active ingredient in

**ECOTRIN® TABLETS\***

REGULAR STRENGTH

ASPIRIN

PAIN RELIEVER (NSAID)

- SAFETY COATED

PROTECT AGAINST

STOMACH UPSET

500 TABLETS



Compare to the active ingredient in  
**ECOTRIN® TABLETS\***

REGULAR STRENGTH

# ASPIRIN

**PAIN RELIEVER (NSAID)**

**SAFETY COATED**

- PROTECTS AGAINST STOMACH UPSET



**500 TABLETS**

**TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

### Drug Facts

**Active ingredient (in each tablet)**

Aspirin (NSAID)<sup>1</sup> 325 mg. <sup>1</sup>nonsteroidal anti-inflammatory drug

**Purpose**

Pain reliever

**Uses**

- Temporarily relieves minor aches and pains due to:
  - headache
  - minor arthritis pain
  - toothache
  - menstrual pain
  - colds
- or as recommended by a doctor

### 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, shock, facial swelling, asthma (wheezing)

### 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 have ever had an allergic reaction 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, or arthritis**

(continued under label)



ITEM#60531-4

0 40232 60531 4

Distributed By:  
Spirit Pharmaceuticals, LLC  
Ronkonkoma, NY 11779  
ORIG 06/17

Lot No.

Exp. Date



### Drug Facts (continued)

**Stop use and ask a doctor if**

- allergic reaction occurs. Seek medical help right away.
- you experience any of the following signs of stomach bleeding:
  - belly pain
  - 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
- any new symptoms appear
- ringing in the ears or a 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

adults and children 12 years of age and over: take 1 to 2 tablets every 4 hours, while symptoms persist. Drink a full glass of water with each dose.  
do not take more than 12 tablets in 24 hours unless directed by a doctor  
children under 12 years of age: ask a doctor

### Other information

store below 25°C (77°F)  
Tamper Evident Feature: Do not use if printed inner-seal beneath cap is missing or broken.

### Inactive ingredients

corn starch, croscarmellose sodium, D&C yellow #10 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, methacrylic acid copolymer, microcrystalline cellulose, mineral oil, polysorbate 80, simethicone, sodium hydroxide, sodium lauryl sulfate, talc, titanium dioxide, triethyl citrate

### Questions or comments? 1(888)333-3792

\*This product is not manufactured or distributed by Prestige Brands, Inc. owner of the registered trademark Ecotrin®

## VALUMEDS ASPIRIN

aspirin tablet, delayed release

### Product Information

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:68210-0025

**Route of Administration**

ORAL

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength |
|--|-------------------|----------|
| ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E) | ASPIRIN           | 325 mg   |

### Inactive Ingredients

| Ingredient Name                         | Strength |
|---|----------|
| STARCH, CORN (UNII: O8232NY3S)          |          |
| CROSCARMELOSE SODIUM (UNII: M28OL1HH48) |          |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)    |          |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8)    |          |

|  |
|--|
| <b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)  |
| <b>METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A</b> (UNII: NX76LV5T8J) |
| <b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)                               |
| <b>MINERAL OIL</b> (UNII: T5L8T28FGP)  |
| <b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)   |
| <b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)  |
| <b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)   |
| <b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)                                    |
| <b>TALC</b> (UNII: 7SEV7J4R1U)   |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)   |
| <b>TRIETHYL CITRATE</b> (UNII: 8Z96QXD6UM)   |

### Product Characteristics

|                 |        |                     |          |
|-----------------|--------|---------------------|----------|
| <b>Color</b>    | orange | <b>Score</b>        | no score |
| <b>Shape</b>    | ROUND  | <b>Size</b>         | 10mm     |
| <b>Flavor</b>   |        | <b>Imprint Code</b> | T        |
| <b>Contains</b> |        |                     |          |

### Packaging

| # | Item Code        | Package Description   | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:68210-0025-0 | 500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 04/17/2018           |                    |

### Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M013                                     | 04/17/2018           |                    |

**Labeler** - SPIRIT PHARMACEUTICALS LLC (179621011)