

VALUMEDS ASPIRIN- aspirin tablet, delayed release
SPIRIT PHARMACEUTICALS LLC

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****PRINCIPAL DISPLAY PANEL**

VALUMEDS™

Compare to the active ingredient in ECOTRIN® TABLETS*

REGULAR STRENGTH

ASPIRIN

PAIN RELIEVER (NSAID)

SAFETY COATED

PROTECT AGAINST

STOMACH UPSET

100 TABLETS

LOT:
EXP:
0 40232 60580 2
60580-2

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

VALUMEDS™ NDC 68210-2500-1
Compare to the active ingredient in Ecotrin® Tablets†

**regular strength
ASPIRIN 325 mg
pain reliever
(NSAID)**

safety coated
• protects against stomach upset
100 tablets (325 mg each)


 Actual Size

VALUMEDS™
regular strength
ASPIRIN 325 mg
pain reliever
(NSAID)

safety coated
• protects against stomach upset
100 tablets
(325 mg each)

Drug Facts (continued)
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)

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, poly sorbate 80, simethicone, sodium hydroxide, sodium lauryl sulfate, talc, titanium dioxide, triethyl citrate.

Questions or comments? 1-888-333-9792

†This product is not manufactured or distributed by Pringle Brands, Inc. owner of the registered trademark Ecotrin®.

Distributed By: Spirit Pharmaceuticals, LLC
Rohinton, MA 01179 OAG 0718

READ AND REPEATEDLY FOR COMPLETE WARNINGS AND INFORMATION

Drug Facts
Active ingredient (in each tablet): Purpose: Pain reliever
Aspirin (NSAID) *aspirin, *acetylsalicylic acid, *acetylsalicylic acid, *acetylsalicylic acid, *acetylsalicylic acid

Uses
• temporarily relieves minor aches and pains due to:
• headache • minor aches and pains • colds • toothache • menstrual pain • cramps • 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, asthma, wheezing, stomach bleeding, and swelling. This product contains a non-aspirin NSAID, ibuprofen (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 thinner (anticoagulant) or steroid drug
• take other drugs containing aspirin or non-aspirin NSAIDs (aspirin, ibuprofen, naproxen, or celecoxib)
• have a history of stomach ulcers or bleeding
• take more or for a longer time than directed

Drug Facts (continued)

Do not use
If you have ever had an allergic reaction to aspirin or any other pain reliever or other medicine.

Ask a doctor before use if
• 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 aspirin
• 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: • black stool • 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
This could be signs of a serious condition.

• 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 explicitly directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	

Product Characteristics

Color	orange	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	T
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-2500-1	1 in 1 CARTON	03/10/2020	
1		100 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)

