ASPIRIN ENTERIC COATED- aspirin 81 mg tablet Allegiant Health

Bio Formula Aspirin 81mg

Active ingredient

Aspirin 81mg (NSAID)*

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever

Uses

for the temporary relief of minor aches and pain or as recommended by your doctor. Because of its delayed action, this product will not provide fast relief of headaches or other symptoms needing immediate relief.

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 severe 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 non presecription 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 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
- anticoagulation (thinning of the blood)
- diabetes
- gout
- arthritis

Stop use and ask a doctor if

• an 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
- new symptoms occur
- ringing in the ears or loss of hearing occurs
- You may report serious side effects to 1-888-952-0050

Pregnancy/Breastfeeding

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 specifically 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

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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 of age: consult a doctor

Other information

• save carton for full directions and warnings

- store at room temperature
- do not use if imprinted safety seal under cap is broken or missing

Inactive ingredients

anhydrous lactose, carnauba wax, croscarmellose sodium, D&C yellow #10 aluminum lake, iron oxide ochre, methacrylic acid copolymer, microcrystalline cellulose, polysorbate 80, silicon dioxide, simethicone, sodium hydroxide, sodium lauryl sulfate, talc, titanium dioxide, triethyl citrate

Principal Display Panel

Bio Formula

ASPIRIN

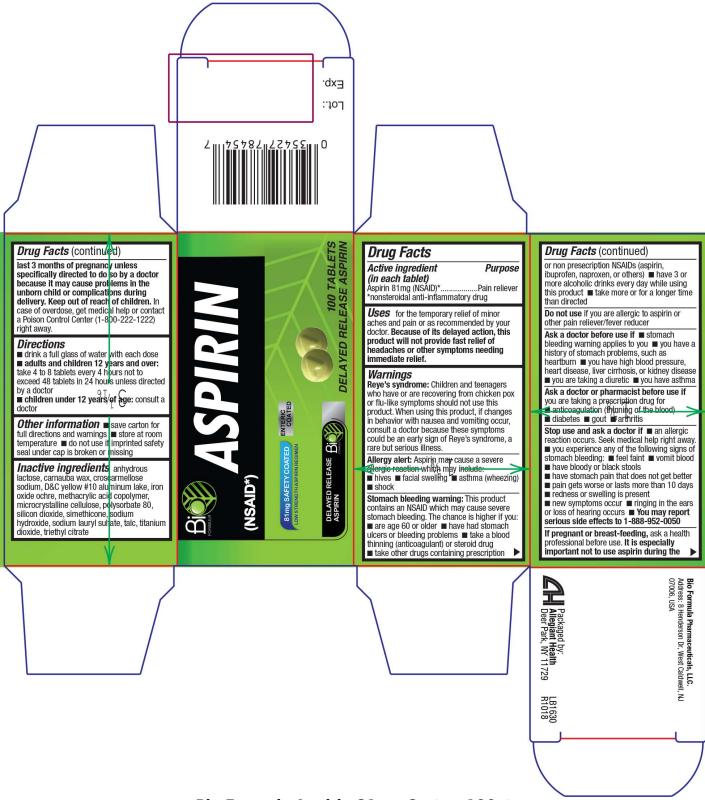
(NSAID*)

81mg SAFETY COATED

ENTERIC COATED

LOW STRENGTH ASPIRIN REGIMEN

DELAYED RELEASE ASPIRIN



Bio Formula Aspirin 81mg Carton 100ct



Bio Formula Aspirin 81mg Label 100ct



Bio Formula Aspirin 81mg Label 300ct

cellulose, polysorbate 80, silicon dioxide

sodium lauryl sulfate, talc,

simethicone, sodium nium dioxide, triethyl

ron oxide ochre, methacrylic acid copolymer, microcrystalline

yellow #10 aluminum

carnau

nactive ingredients anhydrous lactose, rax, croscarmellose sodium, D&C yellow #10 alu

mprinted safety seal under cap is broken or missing Other information
save carton for full directions

■ store at room temperature ■ do not use if

■ drink a full glass of water with each close
■ adults and children 12 years and over: take 4 to 8
tablets every 4 hours not to exceed 48 tablets in 24 hours

Directions

-800-222-1222) right away

delivery. Keep out of reach of children. In case of overdose get medical help or contact a Poison Control Center

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 specifically directed to do so by a doctor because it may cause problems in the unborn child or complications during

■ children under 12 years of age: consult a doctor

occur ■ ringing in the ears or loss of hearing occur's
■ You may report serious side effects to 1-888-952-0050

0 days ■ redness or swe

ling is present ■ new symptoms

Stop use and ask a doctor if an allergic reaction occurs madical halp right away. I you experience any of the

Drug Facts (continued)

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

ASPIRIN **ENTERIC COATED**

aspirin 81 mg tablet

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:69168-318

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	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)		
CARNAUBA WAX (UNII: R12CBM0EIZ)		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)		
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)		
FERRIC OXIDE YELLOW (UNII: EX43802MRT)		
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)		
POLYSORBATE 80 (UNII: 60ZP39ZG8H)		
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 (UNII: 1CS02G8656)		

Product Characteristics				
Color	yellow	Score	no score	
Shape	ROUND	Size	7mm	
Flavor		Imprint Code	A	
Contains				

Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:69168-318- 01	1 in 1 CARTON	12/18/2014			
1		100 in 1 BOTTLE; Type 0: Not a Combination Product				
2	NDC:69168-318- 03	300 in 1 BOTTLE; Type 0: Not a Combination Product	12/18/2014			



Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M013	12/18/2014		

Labeler - Allegiant Health (079501930)

Registrant - Allegiant Health (079501930)

Revised: 11/2018 Allegiant Health