

**ASPIRIN ENTERIC COATED- aspirin 81 mg tablet**  
**Allegiant Health**

-----  
**Drug Facts**

**Active ingredient**

**Aspirin 81 mg (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 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 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 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**

are taking a prescription drug for

- 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

### **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**

In case of accidental 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:** consult a doctor

### **Other Information**

- store at room temperature 20°– 25°C (68°–77°F)
- do not use if imprinted seal under safety cap is broken or missing

### **Inactive Ingredients**

corn starch, croscopvidone, D&C yellow #10 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, methacrylic acid copolymer, microcrystalline cellulose, silicon dioxide, stearic acid, talc, titanium dioxide, triethyl citrate

# Questions and Comments

Call 1-888-952-0050 Monday through Friday 9AM - 5PM

## Package/Label Principal Display Panel

**HealthA2z**® NDC 69168-372-17  
 \*\*COMPARE TO BAYER® LOW DOSE ASPIRIN ACTIVE INGREDIENT  
**ASPIRIN**  
 PAIN RELIEVER (NSAID)  
 ENTERIC COATED  
**81mg SAFETY COATED**  
 LOW STRENGTH ASPIRIN REGIMEN  
**300 TABLETS DELAYED RELEASE ASPIRIN**

Talk to your doctor or other healthcare provider before using this product for your heart.

**Purpose**  
 Pain reliever

**Active ingredient (in each tablet)**  
 Aspirin 81mg (NSAID) \*monosteroidal anti-inflammatory drug

**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 prescription 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 any other pain reliever/fever reducer

**Drug Facts (continued on inside)**  
 L81782 R0324  
 X001Q1UH33  
 HealthA2z Aspirin 81mg Lo...to Bayer Active Ingredient New  
 Lot: Exp:  
**UNVARNISHED**  
 PEEL HERE

Manufactured by: **Allegiant Health**  
 Deer Park, NY 11729

6

**Drug Facts (continued)**

**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) ■ gout ■ diabetes ■ 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

**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.** 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** ■ store at room temperature 20°-25°C (68°-77°F) ■ do not use if imprinted seal under safety cap is broken or missing

**Inactive ingredients** colloidal silicon dioxide, corn starch, croscollon, D&C yellow #10 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, methacrylic acid copolymer, microcrystalline cellulose, stearic acid, talc, titanium dioxide, triethyl citrate

**Questions or comments?**  
 Call 1-888-952-0050 Monday through Friday 9AM - 5PM  
 \*This product is not manufactured or distributed by Bayer HealthCare LLC, owner of the registered trademark Bayer® Low Dose Aspirin.

### Aspirin

ASPIRIN ENTERIC COATED			
aspirin 81 mg tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69168-372
Route of Administration	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>ASPIRIN</b> (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	81 mg

**Inactive Ingredients**

Ingredient Name	Strength
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>CROSPVIDONE</b> (UNII: 2S7830E561)	
<b>D&amp;C YELLOW NO. 10 ALUMINUM LAKE</b> (UNII: CQ3XH3DET6)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1)</b> (UNII: 74G4R6TH13)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TRIETHYL CITRATE</b> (UNII: 8Z96QXD6UM)	

**Product Characteristics**

<b>Color</b>	yellow	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	7mm
<b>Flavor</b>		<b>Imprint Code</b>	A
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-372-50	1 in 1 CARTON	11/11/2020	
1		50 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:69168-372-06	1 in 1 CARTON	11/11/2020	
2		120 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:69168-372-17	300 in 1 BOTTLE; Type 0: Not a Combination Product	11/11/2020	
4	NDC:69168-372-40	1 in 1 CARTON	02/03/2022	
4		40 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:69168-372-99	365 in 1 BOTTLE; Type 0: Not a Combination Product	12/27/2023	

**Marketing Information**

Marketing	Application Number or Monograph	Marketing Start	Marketing End
-----------	---------------------------------	-----------------	---------------

Category	Citation	Date	Date
OTC Monograph Drug	M013	11/11/2020	

**Labeler** - Allegiant Health (079501930)

Revised: 11/2020

Allegiant Health