

ASPIRIN 81MG ENTERIC COATED DELAYED RELEASE- aspirin tablet, coated

Allegiant Health

405 - Aspirin 81mg

Active ingredient(s)

Aspirin 81mg (NSAID)*

Purpose

Pain reliever

Use(s)

- 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.
- ask your doctor about other uses for this product

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 are allergic to aspirin or other pain reliever/fever reducer
- if you have ever had an allergic reaction to this product or any of its ingredients

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

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, colloidal silicon dioxide, croscarmellose sodium, D&C yellow

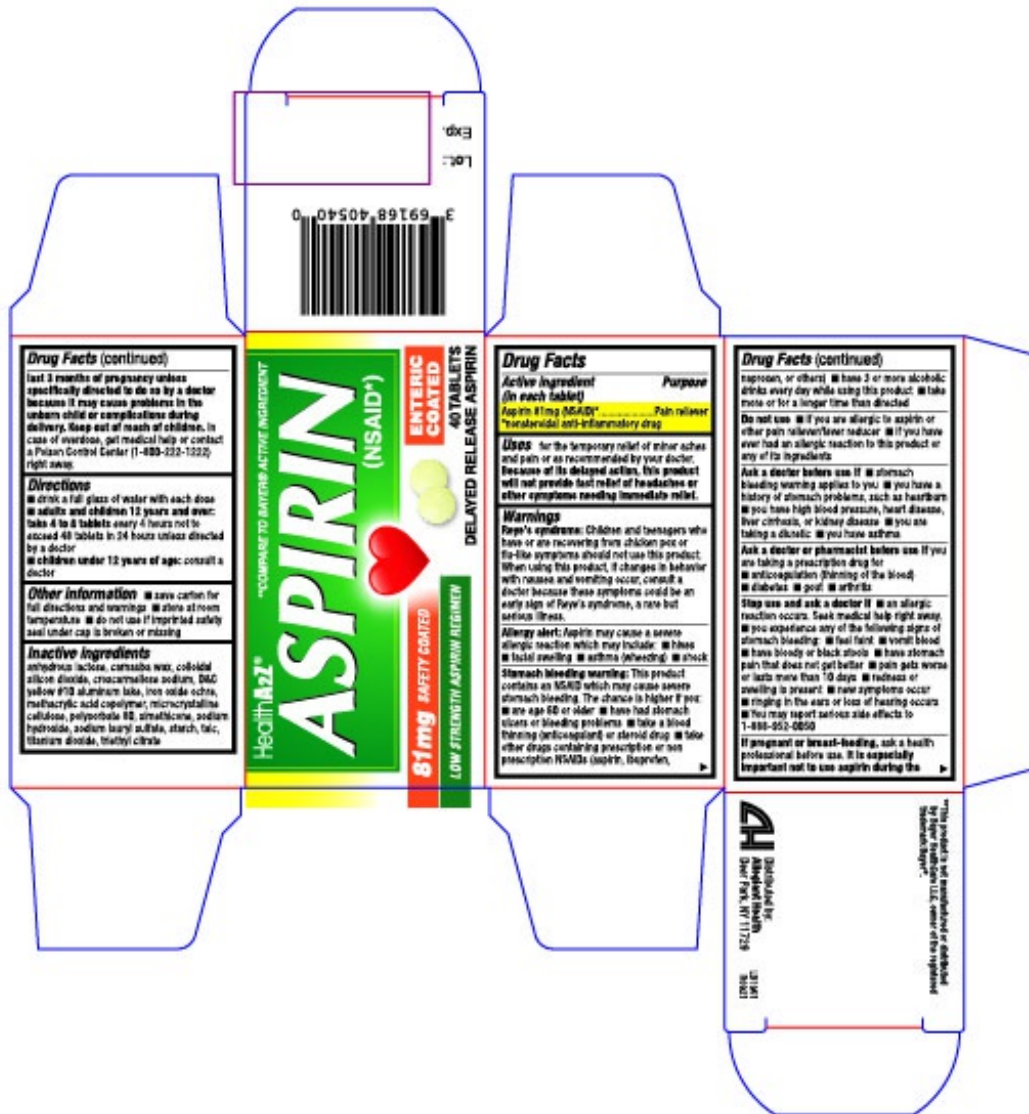
#10 aluminum lake, iron oxide ochre, methacrylic acid copolymer, microcrystalline cellulose, polysorbate 80,

simethicone, sodium hydroxide, sodium lauryl sulfate, starch, talc, titanium dioxide, triethyl citrate

Questions

1-888-952-0050, Monday Through Friday 9am-5pm

Principal Display Panel



Aspirin 81mg

ASPIRIN 81MG ENTERIC COATED DELAYED RELEASE

aspirin tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69168-405
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)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)	
BROWN IRON OXIDE (UNII: 1N032N7MFO)	
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SODIUM HYDRIDE (UNII: 23J3BHR95O)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics

Color	yellow	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	HEART
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-405-40	1 in 1 CARTON	12/15/2021	
1		40 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:69168-405-17	300 in 1 BOTTLE; Type 0: Not a Combination Product	12/15/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC Monograph Drug M013

12/15/2021

Labeler - Allegiant Health (079501930)

Revised: 11/2021

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