

ASPIRIN ENTERIC COATED- aspirin 81 mg tablet
Allegiant Health

Drug Facts

Active ingredient

Aspirin 81 mg (NSAID*)
*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/fever reducer

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 are allergic 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 have asthma you are taking a diuretic

Ask a doctor or pharmacist before use if you are

taking a prescription drug for anticoagulation (thinning 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 side effects to 1-888-952-0050

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 PoisonControl 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

Inactive Ingredients

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

May contain: starch

Package/Label Principal Display Panel



Aspirin

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)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
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 (UNII: 1CS02G8656)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
May contain	STARCH, CORN (UNII: O8232NY3SJ)	

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:69168-318-50	1 in 1 CARTON	12/18/2014	
1		50 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:69168-318-06	1 in 1 CARTON	12/18/2014	
2		120 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:69168-318-17	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)

Revised: 11/2018

Allegiant Health