

ASPIRIN 81 MG- aspirin enteric coated tablets 81 mg tablet, delayed release NewVue LLC

Aspirin 81mg Enteric Coated Tablets

corn starch, pregelatinized starch, povidone, microcrystalline cellulose, colloidal silicon dioxide, stearic acid, methacrylic acid and ethyl acrylate copolymer, talc, titanium dioxide, triethyl citrate, sodium bicarbonate, sodium lauryl sulfate, d&c yellow #10, hypromellose, triacetin

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

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 you have not been drinking fluids you have lost a lot of fluid due to vomiting or diarrhea

Ask a doctor or pharmacist before use if you are - taking a prescription drug for diabetes, gout, or arthritis - taking any other drug - under a doctor's care for any serious condition

Aspirin Drug Facts

Do not use: if you are allergic to aspirin or any other pain reliever/fever reducer

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

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.

Pain reliever

Stop use and ask a doctor if - an allergic reaction occurs. Seek medical help right away. - you are experiencing any of the following signs of stomach bleeding: feel faint, have bloody or black stools, vomit blood, 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 a loss of hearing occurs. these could be signs of a serious condition.

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

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 early sign of Reye's syndrome, a rare but serious illness.

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 longer time than directed

Allergy Alert: Aspirin may cause a severe allergic reaction which may include: - hives - facial swelling - shock - asthma (wheezing)

Pin Reliever

NDC 83813-001-01

****Compare to Bayer® Aspirin active ingredient**

NewVue

ADULT LOW DOSE

Aspirin

Pain Reliever (NSAID)

• safety coated aspirin regimen

• delayed release

• safe pain relief

1000 ENTERIC Coated Tablets

81 mg

actual size

Drug Facts

Active ingredient (in each tablet) Purpose

Aspirin USP, 81 mg (NSAID)*.....Pain reliever

*nonsteroidal anti-inflammatory drug

Uses

■ for 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.

■ ask your doctor about other uses for this product

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

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)

Drug Facts (continued)

■ 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 are taking a diuretic ■ you have asthma

Ask a doctor or pharmacist before use if you 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 for more than 10 days

■ redness or swelling is present ■ new symptoms occur

■ ringing in the ears or 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).

Other Information

■ store between 20°-25°C (68°-77°F) in a dry place

DO NOT USE IF PRINTED SEALUNDER CAP IS BROKEN OR MISSING

Drug Facts (continued)

Inactive ingredients

corn starch, pregelatinized starch, povidone, microcrystalline cellulose, colloidal silicon dioxide, stearic acid, methacrylic acid copolymer, talc, titanium dioxide, triethyl citrate, silica, sodium bicarbonate, sodium lauryl sulfate, d&c yellow # 10, hypromellose, triacetin

Distributed By:

NewVue LLC
Greenville, SC 29607
www.GetNewVue.com

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ASPIRIN 81 MG

aspirin enteric coated tablets 81 mg tablet, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83813-001
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
TRIACETIN (UNII: XHX3C3X673)			
STEARIC ACID (UNII: 4ELV7Z 65AP)			
POVIDONE (UNII: FZ989GH94E)			
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)			
SODIUM LAURYL SULFATE (UNII: 368GB5141J)			
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)			
STARCH, CORN (UNII: O8232NY3SJ)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			

METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:2) (UNII: XRK36F13ZZ)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
SODIUM BICARBONATE (UNII: 8MDF5V39QO)				
TALC (UNII: 7SEV7J4R1U)				
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)				
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)				
Product Characteristics				
Color	yellow	Score	no score	
Shape	ROUND	Size	8mm	
Flavor		Imprint Code	S81	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83813-001-01	1000 in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2021	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013		05/03/2021	

Labeler - NewVue LLC (119120572)

Revised: 11/2023

NewVue LLC