

ASPIRIN 81MG ENTERIC COATED- aspirin tablet, delayed release

Advanced Rx LLC

Active ingredient (in each tablet)

Aspirin 81mg (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 headache 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
- 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:

- 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
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- ringing in the ears or a loss of hearing occurs

If pregnant or breast-feeding,

ask a health professional before use. It is especially important not to use aspirin at 20 weeks or later in 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 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 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

Inactive ingredients

Acrycoat, Colloidal Silicon Dioxide, Croscarmellose Sodium, D&C Yellow# 10, Lactose, Microcrystalline Cellulose, Polysorbate 80, Sodium Hydroxide, Talc, Titanium Dioxide, Triethyl Citrate, Yellow Oxide of Iron.

Questions?

Call toll free 1-800-630-8895

PRINCIPAL DISPLAY PANEL

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Compare to the active ingredient in Bayer® Low Dose Aspirin®
NDC 80513-287-03

Adult Low Dose

ASPIRIN

81 mg

Safety Coated Aspirin Regimen

Pain Reliever (NSAID)**



300 Enteric Coated Tablets

DO NOT USE IF PRINTED SEAL UNDER CAP IS MISSING OR DAMAGED

Drug Facts

Active ingredient (in each tablet) **Purpose**
Aspirin 81 mg (NSAID)** Pain reliever
**nonsteroidal anti-inflammatory drug

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 ■ 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

PEEL FOR DIRECTIONS

287-03-P6 07/25

Drug Facts (continued)

Ask a doctor or pharmacist before use if you are taking a prescription drug for ■ 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
 ■ fever gets worse or lasts more than 3 days
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Questions? call toll-free 1-800-630-8895

*This product is not manufactured or distributed by the owner of the registered trademark Bayer®

Distributed by: **ADVANCED RX LLC**
1942 NE 163rd St
North Miami Beach, FL 33162 U.S.A.

ASPIRIN 81MG ENTERIC COATED

aspirin tablet, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80513-287
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	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)				
LACTOSE (UNII: J2B2A4N98G)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
SODIUM HYDROXIDE (UNII: 55X04QC32I)				
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)				
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)				
Product Characteristics				
Color	yellow	Score	no score	
Shape	ROUND	Size	7mm	
Flavor		Imprint Code	A1	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80513-287-03	300 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2025	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013		05/01/2025	

Labeler - Advanced Rx LLC (042795108)

Registrant - Advanced Rx LLC (042795108)

Establishment

Name	Address	ID/FEI	Business Operations
ELYSIUM PHARMACEUTICALS LIMITED		915664486	manufacture(80513-287)