

ASPIRIN 81 MG- aspirin tablet, coated
A-S Medication Solutions

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Aspirin 81mg EC

Active ingredient (in each tablet)

Aspirin 81 mg (NSAID*)

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever

Uses

temporarily relieves minor aches and pains

Because of its delayed action, this product will not produce fast relief of headaches or other symptoms needing immediate relief.

ask your doctor about other uses for enteric-coated 81 mg Aspirin

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 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
- shock
- asthma (wheezing)

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, naprozen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for longer time than directed

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

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

Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away.
- you are experiance 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.

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.

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 premitted between 15°-30°C (59°-86°F)
- Use by expiration date on package

Inactive ingredients

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

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

Drug Facts

HOW SUPPLIED

Product: 50090-5476

NDC: 50090-5476-3 90 TABLET, COATED in a BOTTLE

ASPIRIN 81 MG (ASPIRIN) TABLET, COATED



ASPIRIN 81 MG

aspirin tablet, coated

Product Information

Product Type		HUMAN OTC DRUG	Item Code (Source)	NDC:50090-5476(NDC:69618-066)		
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	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)						
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)						
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)						
TALC (UNII: 7SEV7J4R1U)						
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)						
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)						
SODIUM BICARBONATE (UNII: 8MDF5V39QO)						
SODIUM LAURYL SULFATE (UNII: 368GB5141J)						
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)						
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)						
STEARIC ACID (UNII: 4ELV7Z65AP)						
STARCH, CORN (UNII: O8232NY3SJ)						
Product Characteristics						
Color		yellow	Score	no score		
Shape		ROUND	Size	5mm		
Flavor			Imprint Code	17;S		
Contains						
Packaging						
#	Item Code	Package Description		Marketing Start Date	Marketing End Date	
1	NDC:50090-5476-3	90 in 1 BOTTLE; Type 0: Not a Combination Product		03/04/2021		

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 ■ 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

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 ● 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.

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STOP PEELING

ADULT LOW STRENGTH

Reliable-1®

NDC 69618-066-02

120 Tablets

Compare to Active Ingredient in Aspirin Regimen BAYER®

ENTERIC COATED

81 MG (NSAID)

Pain Reliever Aspirin USP

1Reliable-1 Laboratories is not affiliated with the owner of the trademark BAYER®. Distributed by: Reliable-1 Laboratories LLC Rev. 00 Valley Stream, NY 11580 www.reliable1labs.com 516-341-0666

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TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING

Drug Facts

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

Uses ■ temporarily relieves minor aches and pains
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 enteric-coated 81 mg Aspirin

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.
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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

PEEL HERE FOR MORE DRUG FACTS

LOT #:

EXP. DATE:

UNVARNISHED AREA

Drug Facts continued on back of label

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	10/01/2020	

Labeler - A-S Medication Solutions (830016429)

Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-5476) , REPACK(50090-5476)

Revised: 5/2021

A-S Medication Solutions