

ASPIRIN 81- aspirin tablet
Rising Health, LLC

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 81 mg

DRUG FACTS

Active ingredient (in each tablet)

Aspirin 81 mg (NSAID)#

#nonsteroidal anti-inflammatory drug

Purpose

Pain reliever

Uses

- temporarily relieves minor aches and pains
- 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.

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 are taking a diuretic

- you have asthma

Ask a doctor or pharmacist before use if you are taking a prescription drug for gout, diabetes or 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
- ringing in the ears or a loss of hearing occurs
- redness or swelling is present
- new symptoms occur. 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 (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: do not use unless directed by a doctor

Other information

- Store at 20-25°C (68-77°F)
- close cap tightly after use

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, D&C yellow#10, FD&C yellow#6, methacrylic acid copolymer, microcrystalline cellulose, silicon dioxide, stearic acid, talcum, titanium dioxide, triethyl citrate

Questions or comments? Call 1-844-474-7464

Rising Health

Aspirin 81 mg

NDC 57237-302-10

1000 Tablets

Rising[®] HEALTH NDC 57237-302-10

*Compare to the active ingredient in Bayer[®] Low Dose Aspirin

Aspirin 81 mg

Pain Reliever (NSAID)

- Enteric Coated
- Low Dose



**Talk to your doctor or other healthcare provider before using this product for your heart.

1000 Tablets

DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Drug Facts

Active Ingredients (in each tablet)
 aspirin (acetylsalicylic acid).....Pain reliever
 hydrocodone bitartrate.....Anesthetics
 acetaminophen.....Pain reliever

Uses ■ Temporarily relieves minor aches and pain
 ■ Ask your doctor about other uses for enteric coated 81 mg Aspirin.

Warnings
 ■ **Heart Disease:** 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.
 ■ **Aspirin:** Aspirin may cause a severe allergic reaction which may include:
 ■ 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
 ■ are taking a 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 are taking aspirin or other pain relievers such as heartburn medicine, aspirin, ibuprofen, naproxen, or other NSAIDs
 ■ 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 or 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 go away
 ■ pain gets worse or lasts more than 10 days
 ■ ringing in the ears or a loss of hearing occurs
 ■ redness or swelling is present
 ■ new symptoms occur. 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 instructed by a doctor. Aspirin may harm the fetus or 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 32 tablets in 24 hours unless directed by a doctor
 ■ children under 12 years: do not use unless directed by a doctor

Other information
 ■ Store at 20-25°C (68-77°F) ■ close cap tightly after use

Inactive Ingredients
 colloidal silicon dioxide, croscarmellose sodium, D&C yellow#10, FD&C yellow#6, methacrylic acid copolymer, microcrystalline cellulose, silicon dioxide, stearic acid, talcum, titanium dioxide, triethyl citrate

Questions or comments? Call 1-844-474-7464

*This product is not manufactured or distributed by Bayer, owner of registered trademark of Bayer[®] Low Dose Aspirin.

Lot: 0822
 Issued: 08/22
 Exp Date: **SPOT UV**



ASPIRIN 81

aspirin tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57237-302
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)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
METHACRYLIC ACID (UNII: 1CS02G8656)	
TALC (UNII: 7SEV7J4R1U)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
TITANIUM DIOXIDE (UNII: 15F1X9V2JP)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	yellow	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	11;Plain

Contains**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57237-302-12	120 in 1 BOTTLE; Type 0: Not a Combination Product	10/25/2022	
2	NDC:57237-302-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	10/25/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	10/25/2022	

Labeler - Rising Health, LLC (080500961)**Establishment**

Name	Address	ID/FEI	Business Operations
Invahealth Inc.		116840615	manufacture(57237-302) , analysis(57237-302) , label(57237-302) , pack(57237-302)

Revised: 10/2022

Rising Health, LLC