ADULT LOW DOSE- aspirin 81 mg tablet, delayed release
Safrel Pharmaceuticals, 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 Enteric Coated Tablets

Drug Facts

Active Ingredients (in each tablet) **Purpose**

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

*nonsteroidal anti-inflammatory drug

Uses

- 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 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
- shock
- facial swelling
- 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, 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
- you have asthma
- 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

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

Stop use and ask a doctor if
- 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
- an allergic reaction occurs.

Seek medical help right away.
- ringing in the ears or loss of hearing occurs
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days
- redness or swelling present in the painful area
- new symptoms occur

These could be sign 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. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

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 room temperature 15-30ºC (59-86ºF)
- read all product information before using.
- Keep this box for important information
- **TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

Inactive ingredients

Anhydrous Lactose, Carnuba Wax Colloidal Sillicon Dioxide, Crosscarmellose Sodium,FD&C Yellow #10 al lake, FD&C Yellow#6 al Lake, Iron Oxide Ochre, Methacrylic acid copolymer, Micro crystalline cellulose, Polysorbate 80, simethiocone, sodium hydroxide, sodium lauryl sulfate, talc, titanium dioxide, triethyl citrate

Questions or comments?

Call toll free 1-844-384-3723 Monday through Friday 9AM – 5PM EST or www.safrel.com

PRINCIPAL DISPLAY PANEL

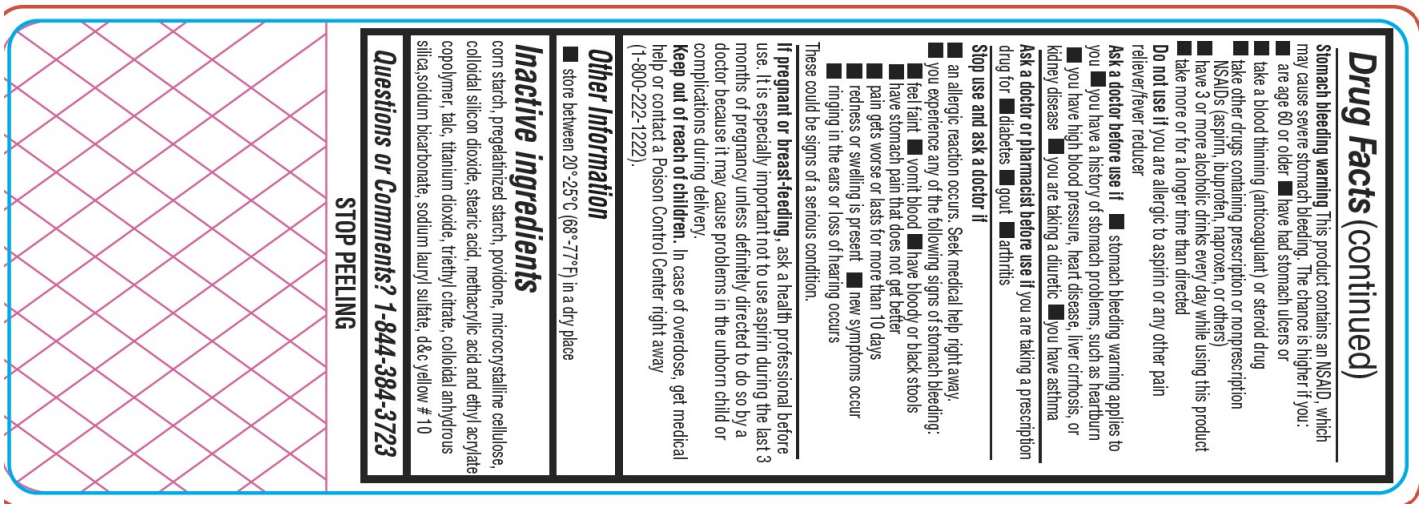
See New Warnings Information & Directions

Compare to Bayer® Low Dose Aspirin active ingredients†

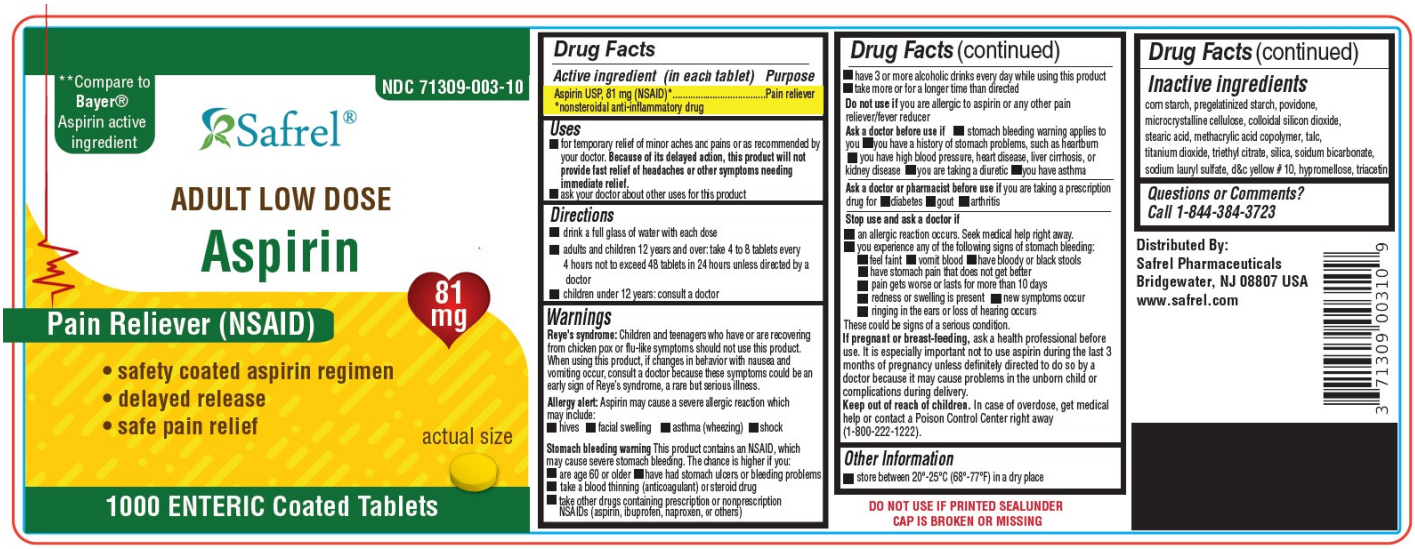
† This product is not manufactured or distributed by Bayer HealthCare LLC., owner of the registered trademark Bayer® Low Dose Aspirin.

Aspirin Enteric Coated Tablets, 81 mg

NDC 71309-003-05



NDC 71309-003-10



ADULT LOW DOSE

aspirin 81 mg tablet, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71309-003

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
CARNAUBA WAX (UNII: R12CBM0EIZ)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
BROWN IRON OXIDE (UNII: 1N032N7MFO)	
METHACRYLIC ACID (UNII: 1CS02G8656)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TALC (UNII: 7SEV7J4R1U)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

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:71309-003-25	25 in 1 BOX	06/05/2017	
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:71309-003-50	50 in 1 BOX	06/05/2017	
2		2 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:71309-003-02	2 in 1 POUCH	06/05/2017	
3		2 in 1 POUCH; Type 0: Not a Combination Product		
4	NDC:71309-003-05	500 in 1 BOTTLE	01/09/2021	

4	NDC:71309-003-01	1000 in 1 BOTTLE		
4	NDC:71309-003-65	365 in 1 BOTTLE		
4	NDC:71309-003-30	30 in 1 BOTTLE		
4		1 in 1 CARTON; Type 0: Not a Combination Product		
5	NDC:71309-003-60	1 in 1 CARTON	06/05/2017	
5		60 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:71309-003-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	02/09/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	02/09/2016	

Labeler - Safrel Pharmaceuticals, LLC. (080566287)

Revised: 3/2023 Safrel Pharmaceuticals, LLC.