

**ADULT LOW DOSE ASPIRIN ENTERIC SAFETY COATED- aspirin tablet, delayed release
Zandi 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.

DRUG FACTS

Active ingredient (in each tablet)	Purpose
Aspirin 81 mg (NSAID*).....	Pain reliever

*nonsteroidal anti-inflammatory drug

Uses

- for the temporarily relief of minor aches and pains or as recommended by your doctor. Because of its delayed action, this product may not provide fast relief of headache or other symptoms needing immediate relief.
- ask your doctor about other uses of this product

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
- 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, 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, 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
 - have bloody or black stools
 - vomit blood
 - 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 in the painful area
- any new symptoms appear
- 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; do not exceed 48 tablets in 24 hours unless directed by a doctor
- children under 12 years: consult a doctor

- store between 20° - 25°C (60° - 77°F) in a dry place

Inactive ingredients anhydrous lactose, carnauba wax, colloidal silicon dioxide, croscarmellose sodium, D & C yellow # 10, iron oxide ochre, methacrylic acid copolymer, microcrystalline cellulose, polysorbate 80, simethicone, sodium hydroxide, sodium lauryl sulfate, talc, titanium dioxide, triethyl citrate

1000 Enteric Coated Tablets

SEE NEW WARNINGS INFORMATION

†Compare to the active ingredient in Bayer® Low Dose Aspirin

Pain Reliever (NSAID)

**ENTERIC COATED
ASPIRIN**
ADULT LOW DOSE **81 mg**



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

†This product is not manufactured or distributed by Bayer Healthcare, distributor of Bayer® Low Dose Aspirin.



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- ask your doctor about other uses for this product

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 ■ 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, naproxen, or others)

■ have 3 or more alcoholic drinks every day while using this product

■ take more or for a longer time than directed ▼

Distributed by:

ZANDI LLC

Distribution and Export Co.
18375 Ventura Blvd #245,
Tarzana, CA 91356 **USA**
www.zandillc.com

PEEL HERE FOR
ADDITIONAL
DRUG
FACTS

ADHESIVE

Inactive ingredients anhydrous lactose, carnauba wax, colloidal silicon dioxide, croscarmellose sodium, D&C yellow #10, iron oxide ochre, methacrylic acid copolymer, microcystalline cellulose, polysorbate 80, simethicone, sodium hydroxide, sodium lauryl sulfate, talc, titanium dioxide, triethyl citrate

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

- children under 12 years: consult a doctor every 4 hours; do not exceed 48 tablets in 24 hours
- adults and children 12 years and over: take 4 to 8 tablets ■ drink a full glass of water with each dose

Directions

away (1-800-222-1222).
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right during delivery.

cause problems in the unborn child or complications definitely directed to do so by a doctor because it may use aspirin during the last 3 months of pregnancy unless professional before use. It is especially important not to **If pregnant or breast-feeding,** ask a health

- ringing in the ears or loss of hearing occurs
- new symptoms occur
- redness or swelling is present
- pain gets worse or lasts for more than 10 days
- have bloody or black stools
- bleeding: ■ feel faint ■ vomit blood
- you experience any of the following signs of stomach ■ an allergic reaction occurs. Seek medical help right away.

Stop use and ask a doctor if

- diabetes ■ gout ■ arthritis
- taking a prescription drug for:
- Ask a doctor or pharmacist before use if you are**
- you are taking a diuretic ■ you have asthma
- cirrhosis, or kidney disease
- you have high blood pressure, heart disease, liver
- stomach bleeding warning applies to you
- Ask a doctor before use if**
- you have a history of stomach problems, such as heartburn
- any other pain reliever/fever reducer

Do not use if you have ever had an allergic reaction to

Drug Facts (continued)

ADULT LOW DOSE ASPIRIN ENTERIC SAFETY COATED

aspirin tablet, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75942-001
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
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
METHACRYLIC ACID (UNII: 1CS02G8656)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics

Color	yellow	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	embossed;upper;8;lower;plain
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75942-001-12	120 in 1 BOTTLE, PLASTIC		
2	NDC:75942-001-36	360 in 1 BOTTLE, PLASTIC		
3	NDC:75942-001-50	500 in 1 BOTTLE, PLASTIC		
4	NDC:75942-001-75	750 in 1 BOTTLE, PLASTIC		

5	NDC:75942-001-10	1000 in 1 BOTTLE, PLASTIC		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part343	01/18/2011		

Labeler - Zandi LLC (784431590)

Revised: 1/2011

Zandi LLC