

ASPIRIN 81 MG ENTERIC COATED- aspirin tablet
Reliable 1 Laboratories 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 USP 81mg Enteric Coated Tablet

Drug Facts

Active ingredients (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 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.

Allergy alert: Aspirin may cause a severe allergic reaction, which any include:

- hives
- facial swelling
- shock
- asthma (wheezing)

Stomach bleeding warning: This product contains 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
- 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.

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

Inactive ingredients

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

Questions or comments?

call **516-341-0666**, 8:30 am - 4:30 pm ET, Monday - Friday

NDC 69618-046-10

Enteric Coated

Aspirin USP 81mg (NSAID

Adult Low Strength

PAIN RELIEVER

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN

1000 TABLETS

NDC 69618-046-02

R Reliable-1™
LABORATORIES

Enteric Coated
Aspirin USP
81 mg (NSAID)

Adult Low Strength
PAIN RELIEVER

120 TABLETS

†Compare to Active Ingredient in Aspirin Regimen BAYER®

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

3 69618 04602 3
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

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Aspirin 81 mg (NSAID)*, Pain reliever
*nonsteroidal anti-inflammatory drug

Purpose
Pain reliever

Uses
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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

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LOT #: _____
EXP. DATE: _____
PEEL HERE FOR MORE DRUG FACTS

Drug Facts (continued)

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STOP PEELING

ASPIRIN 81 MG ENTERIC COATED

aspirin tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69618-046
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)		
DIMETHICONE (UNII: 92RU3N3Y1O)		
TALC (UNII: 7SEV7J4R1U)		
IRON (UNII: E1UOL152H7)		
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8)		

MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics

Color	yellow	Score	no score
Shape	ROUND	Size	5mm
Flavor		Imprint Code	Heart
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69618-046-02	120 in 1 BOTTLE; Type 0: Not a Combination Product	05/10/2018	
2	NDC:69618-046-10	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/10/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	05/10/2018	

Labeler - Reliable 1 Laboratories LLC (079718111)

Registrant - Reliable 1 Laboratories LLC (079718111)