

**ASPIRIN 81 MG ENTERIC COATED- aspirin tablet**  
**Quality Care Products, 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.*

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**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 may include:

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

**Somach 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

Packaged and Distributed by
*Quality Care Products, LLC*
1-800-337-8603



Holland, OH 43528

**ASPIRIN 81 MG EC**

GTIN: 00355700746605

NDC: 55700-0746-60

Serial:

Lot:

EXP: //

Each tablet contains Aspirin

Distributed by: Reliable-1 Laboratories LLC, Valley Stream, NY 11580

**#60 TABLETS**

Pain Reliever, NSAID

\*nonsteroidal anti-inflammatory drug

Warning: Keep out of children's reach.  
Store at controlled temperature 59-86 degrees F.  
Consult with a physician. See manufacturer's insert.

YELLOW, ROUND, LOGO



ASPIRIN 81 MG EC

#60 TABLETS

Lot:                   EXP: //

NDC: 55700 0746 60

ASPIRIN 81 MG EC

#60 TABLETS

Lot:                   EXP: //

NDC: 55700 0746 60

SOURCE CODE : 5961804602



**ASPIRIN 81 MG ENTERIC COATED**

aspirin tablet

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55700-746(NDC:69618-046)
<b>Route of Administration</b>	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
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>IRON</b> (UNII: E1UOL152H7)	
<b>METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A</b> (UNII: NX76LV5T8J)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TRIETHYL CITRATE</b> (UNII: 8Z96QXD6UM)	

## Product Characteristics

<b>Color</b>	yellow	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	5mm
<b>Flavor</b>		<b>Imprint Code</b>	Heart
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55700-746-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	04/26/2019	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	04/26/2019	

**Labeler** - Quality Care Products, LLC (831276758)

## Establishment

Name	Address	ID/FEI	Business Operations
Quality Care Products, LLC		831276758	repack(55700-746)