

**ASPIRIN ENTERIC SAFETY-COATED- aspirin tablet**  
**AmerisourceBergen (Good Neighbor Pharmacy) 46122**

*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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**Drug Facts**

**Active ingredient (in each tablet)**

**Aspirin 81 mg (NSAID)\***

**\*nonsteroidal anti-inflammatory drug**

**Purpose**

**Pain reliever**

**Uses**

- for the 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 safety 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)

**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.
- if you have ever had an allergic reaction to this product or any of its ingredients

**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 have asthma
- you are taking a diuretic

### **Ask a doctor or pharmacist before use if you are**

taking a prescription drug for

- gout
- diabetes
- 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
- ringing in the ears or loss of hearing occurs
- 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: consult a doctor

### **Other information**

- store between 15-30°C (59-86°F)

### **Inactive ingredients**

D&C yellow #10, FD&C yellow #6, methacrylic acid copolymer, microcrystalline cellulose, pregelatinized starch (corn), silicon dioxide, sodium bicarbonate, sodium lauryl sulfate, stearic acid, talc, titanium dioxide, triethyl citrate

## Questions or comments?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

## Principal Display Panel

Compare to Bayer® Low Dose Aspirin active ingredient†

Low Dose Safety Coated≠≠

Aspirin 81 mg

±aspirin regimen

## Pain reliever (NSAID)

enteric coated tablets

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

≠Talk to your doctor or other healthcare provider before using this product for your heart. Aspirin is not right for everyone.

≠≠Coating helps protect against stomach upset

**TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.**

**KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.**

Distributed By AmerisourceBergen

1300 Morris Drive, Chesterbrook, PA 19087

[www.mygnp.com](http://www.mygnp.com)

## Product Label



Compare to Bayer® Low Dose Aspirin active ingredient\*

NDC 46122-615-76

Low Dose Safety Coated\*\*

# Aspirin 81 mg

\*aspirin regimen

**Pain Reliever (NSAID)**

120 enteric coated tablets

actual size



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ABC#10221283



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PLD-D567A  
FC005699

Lot / Exp.:  
Product of:

# ASPIRIN ENTERIC SAFETY-COATED

aspirin tablet

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:46 122-615
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	81 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TALC (UNII: 7SEV7J4R1U)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

## Product Characteristics

<b>Color</b>	YELLOW	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	7mm
<b>Flavor</b>		<b>Imprint Code</b>	E
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46 122-615-87	1 in 1 BOX	05/31/2019	
1		300 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:46 122-615-76	1 in 1 BOX	05/31/2019	
2		120 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	05/31/2019	

**Labeler** - AmerisourceBergen (Good Neighbor Pharmacy) 46122 (007914906)

Revised: 5/2019

AmerisourceBergen (Good Neighbor Pharmacy) 46122