

**BAYER LOW DOSE- aspirin tablet**  
**Bayer HealthCare 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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**Bayer<sup>®</sup> Low Dose Aspirin Regimen**

***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 Bayer 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
- asthma (wheezing)
- shock

**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
- diabetes
- arthritis

**Stop use and ask a doctor if**

- an allergic reaction occurs. Seek medical right away.
- you experience any of the following signs of stomach bleeding:
  - feel faint
  - vomit blood
  - have bloody or black stools
  - 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

**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**

- save carton for full directions and warnings
- store at room temperature

**Inactive ingredients**

black iron oxide, brown iron oxide, carnauba wax, corn starch, D&C yellow #10 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, methacrylic acid copolymer type C, polysorbate 80, powdered cellulose, propylene glycol, shellac, sodium lauryl sulfate, triacetin, triethyl citrate

**Questions or comments?**

**1-800-331-4536** (Mon - Fri 9AM - 5PM EST) or [www.bayeraspirin.com](http://www.bayeraspirin.com)

**PRINCIPAL DISPLAY PANEL - 32 Tablet Bottle Carton**

*N 0280-2100-32*

***ASPIRIN REGIMEN***

***BAYER***®

*ASPIRIN (NSAID) PAIN RELIEVER*

***LOW DOSE***

***81mg***

***Safety Coated***

***Aspirin***

***32 ENTERIC COATED TABLETS***



<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0280-2100
<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
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
BROWN IRON OXIDE (UNII: 1N032N7MFO)	
STARCH, CORN (UNII: O8232NY3SJ)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
ALUMINUM OXIDE (UNII: LM26O6933)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TRIACETIN (UNII: XHX3C3X673)	
TRIETHYL CITRATE (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>	81
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0280-2100-32	1 in 1 CARTON	07/12/2002	
1		32 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0280-2100-12	1 in 1 CARTON	07/12/2002	
2		120 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:0280-2100-20	1 in 1 CARTON	07/12/2002	
3		200 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:0280-2100-30	1 in 1 CARTON	07/12/2002	
4		300 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:0280-2100-40	1 in 1 CARTON	07/12/2002	
5		400 in 1 BOTTLE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	07/12/2002	

**Labeler** - Bayer HealthCare LLC. (112117283)

## Establishment

Name	Address	ID/FEI	Business Operations
Bayer HealthCare LLC Consumer Care		072827066	manufacture(0280-2100) , pack(0280-2100)

Revised: 9/2017

Bayer HealthCare LLC.