

**BAYER LOW DOSE- aspirin tablet**  
**Bayer HealthCare LLC.**

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**Bayer® 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
<b>ASPIRIN</b> (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	81 mg

**Inactive Ingredients**

Ingredient Name	Strength
<b>FERROSO FERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>BROWN IRON OXIDE</b> (UNII: 1N032N7MFO)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A</b> (UNII: NX76LV5T8J)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>POWDERED CELLULOSE</b> (UNII: SMD1X3XO9M)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SHELLAC</b> (UNII: 46N107B71O)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>TRACETIN</b> (UNII: XHX3C3X673)	
<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>	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 Drug	M013	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: 11/2023

Bayer HealthCare LLC.