

BAYER LOW DOSE- aspirin tablet
Bayer HealthCare LLC, Consumer Care

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.

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

PRINCIPAL DISPLAY PANEL - 32 Tablet Bottle Carton

N 0280-2100-32

ASPIRIN REGIMEN

BAYER®

ASPIRIN (NSAID) PAIN RELIEVER

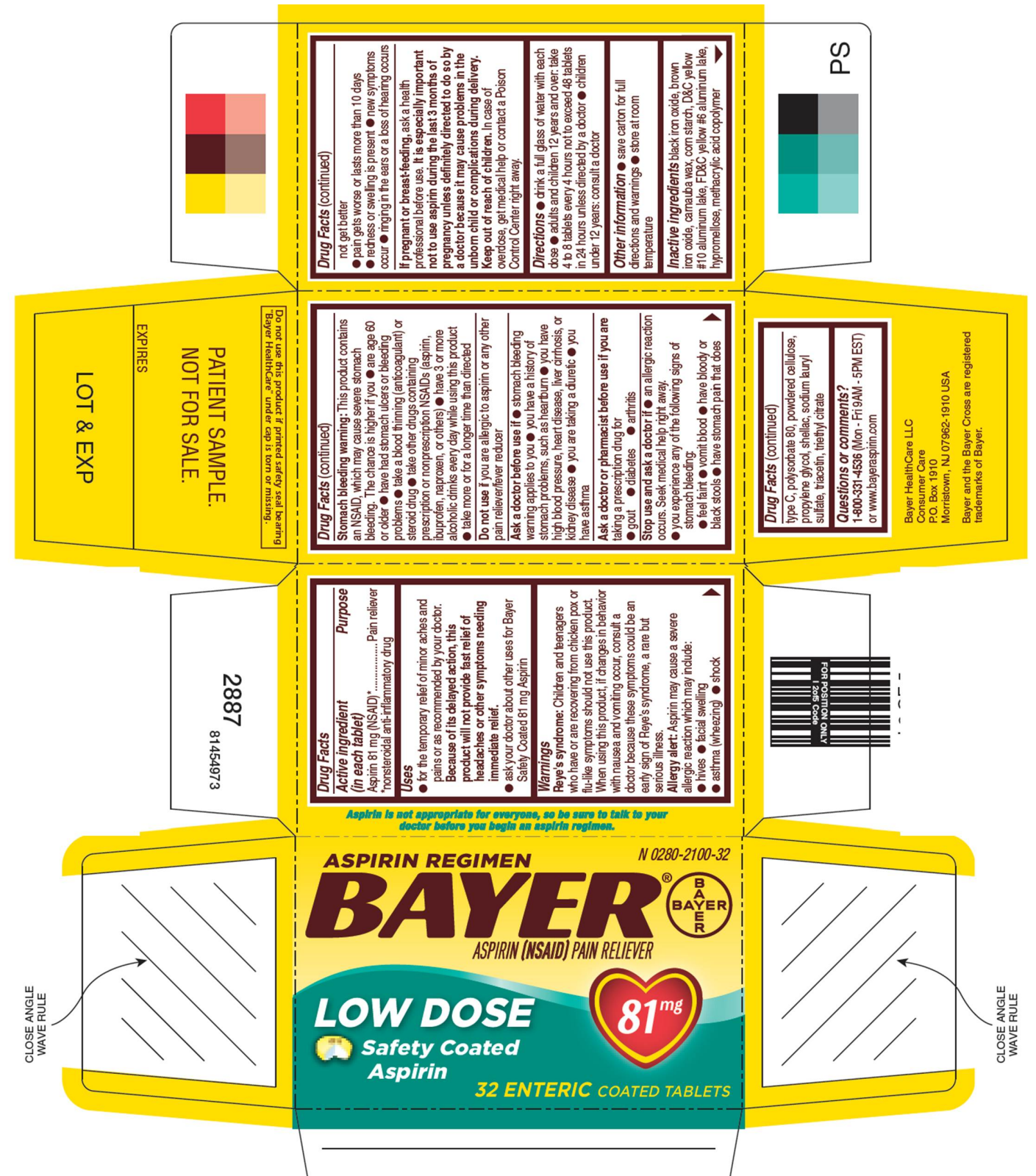
LOW DOSE

81mg

Safety Coated

Aspirin

32 ENTERIC COATED TABLETS



BAYER LOW DOSE

aspirin tablet

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:0280-2100

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
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

Color	yellow	Score	no score
Shape	ROUND	Size	5mm
Flavor		Imprint Code	81
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0280-2100-32	1 in 1 CARTON		
1		32 in 1 BOTTLE		
2	NDC:0280-2100-12	1 in 1 CARTON		
2		120 in 1 BOTTLE		
3	NDC:0280-2100-20	1 in 1 CARTON		
3		200 in 1 BOTTLE		
4	NDC:0280-2100-30	1 in 1 CARTON		
4		300 in 1 BOTTLE		
5	NDC:0280-2100-40	1 in 1 CARTON		
5		400 in 1 BOTTLE		

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, Consumer Care (785159372)

Establishment

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

Revised: 11/2014

Bayer HealthCare LLC, Consumer Care