

**BAYER BACK AND BODY EXTRA STRENGTH- aspirin,caffeine tablet**  
**Bayer HealthCare LLC.**

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**Bayer Back & Body - Extra Strength**

***Drug Facts***

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***Active ingredients (in each caplet)***

<b><i>Active ingredients (in each caplet)</i></b>	<b><i>Purpose</i></b>
Aspirin 500 mg (NSAID) *	Pain reliever
Caffeine 32.5 mg	Pain reliever aid

\* nonsteroidal anti-inflammatory drug

***Purpose***

***Uses***

for the temporary relief of

- backache pain
- muscle aches and pains
- minor aches and pains of arthritis

***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
- 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 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 help 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 2 caplets every 6 hours not to exceed 8 caplets in 24 hours
- children under 12 years: consult a doctor

***Other Information***

- save carton for full directions and warnings
- store at room temperature. Avoid excessive heat above 40°C (104°F).

***Inactive Ingredients***

carnauba wax, corn starch, D&C red #30 aluminum lake, D&C yellow #10 aluminum lake, hypromellose, powdered cellulose, propylene glycol, shellac, titanium dioxide, triacetin

***Questions or comments? 1-800-331-4536*** (Mon-Fri 9AM - 5PM EST)



Route of Administration		ORAL		
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)		CAFFEINE	35.5 mg	
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)		ASPIRIN	500 mg	
Inactive Ingredients				
Ingredient Name			Strength	
STARCH, CORN (UNII: O8232NY3SJ)				
D&C RED NO. 30 (UNII: 2S42T2808B)				
ALUMINUM OXIDE (UNII: LMI26O6933)				
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)				
HYPROMELLOSES (UNII: 3NXW29V3WO)				
POWDERED CELLULOSE (UNII: SMD1X3XO9M)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
SHELLAC (UNII: 46N107B71O)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
CARNAUBA WAX (UNII: R12CBM0EIZ)				
TRIACETIN (UNII: XHX3C3X673)				
Product Characteristics				
Color	white	Score	no score	
Shape	OVAL	Size	19mm	
Flavor		Imprint Code	BAYER;BACK;BODY	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0280-2150-24	1 in 1 CARTON	01/12/2015	
1		24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:0280-2150-50	1 in 1 CARTON	01/12/2015	
2		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:0280-2150-10	1 in 1 CARTON	01/12/2015	
3		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
4	NDC:0280-2150-02	200 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/12/2015	
5	NDC:0280-2150-01	1 in 1 CARTON	01/12/2015	
5		6 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

6	NDC:0280-2150-03	250 in 1 BOTTLE; Type 0: Not a Combination Product	01/12/2015	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013		01/12/2015	

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

Revised: 4/2025

Bayer HealthCare LLC.