

**BAYER BACK AND BODY EXTRA STRENGTH- aspirin,caffeine 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 Back & Body - Extra Strength**

***Drug Facts***

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

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Aspirin 500 mg (NSAID) \*

Caffeine 32.5 mg

\* nonsteroidal anti-inflammatory drug

***Purpose***

Pain reliever

Pain reliever aid

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***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***

caruba 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)

5/8"

**Drug Facts (continued)**  
 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  
 ● pain gets worse or lasts more than 10 days  
 ● fever gets worse or lasts more than 3 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 4 hours not to exceed 8 caplets in 24 hours  
 ● children under 12 years: consult a doctor  
**Other information**  
 ● see caution for full directions and warnings  
 ● store at room temperature. Avoid excessive heat above 40°C (104°F)  
**Inactive ingredients** caruba 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)

PS

LOT & EXP AREA

EXPIRES

3 12843 55540 2

FPO, 100% UPC

**Drug Facts**  
**Active ingredients (in each caplet)**  
 Aspirin 500 mg (NSAID) Pain reliever  
 Caffeine 32.5 mg Pain reliever and  
 transdermal anti-inflammatory drug  
**Uses** for the temporary relief of:  
 ● moderate 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 can cause 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 take asthma

PS

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ASPIRIN (NSAID)/PAIN RELIEVER CAFFEINE/PAIN RELIEVER AID

**BAYER**

**EXTRA STRENGTH**  
**FAST RELIEF AT THE SITE OF PAIN**

**BACK & BODY**

- RUSHES RELIEF TO THE SITE OF TOUGH PAIN
- RELIEVES BACKACHES AND ACHING MUSCLES
- COATED FOR EASIER SWALLOWING

23/32" 12 OF 5 CODE AREA REQUIRES 1/4" QUIET ZONE

PS

WAVE PATTERN

WAVE RULE

ASPIRIN (NSAID)/PAIN RELIEVER CAFFEINE/PAIN RELIEVER AID

**BAYER**

**BACK & BODY**

**EXTRA STRENGTH**  
**FAST RELIEF AT THE SITE OF PAIN**

**500 mg** **100** COATED CAPLETS

PS

**BAYER BACK AND BODY EXTRA STRENGTH**  
 aspirin, caffeine tablet

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0280-2150
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	35.5 mg
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	500 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
STARCH, CORN (UNII: O8232NY3SJ)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
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**

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	BAYER;BACK;BODY
<b>Contains</b>			

**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	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	01/12/2015	

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

Revised: 8/2017

Bayer HealthCare LLC.