

**BAYER HEADACHE- aspirin and caffeine tablet**  
**Bayer HealthCare LLC.**

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**Bayer Headache UI 1600654**

***Drug Facts***

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

Aspirin 500 mg (NSAID)\*.....Pain reliever/fever reducer

Caffeine 32.5 mg.....Pain reliever aid

\*nonsteroidal anti-inflammatory drug

**Uses**

***Uses***

- temporarily relieves minor aches and pains due to:
  - headache
  - toothache
  - colds
  - muscle pain
  - minor pain of arthritis
- temporarily reduces fever

***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
- 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 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)

**Package Display 50 Count Carton**

**Bayer®**

**ASPIRIN (NSAID)/PAIN RELIEVER/FEVER REDUCER CAFFEINE/PAIN RELIEVER  
AID**

**Headache**

**FAST RELIEF AT THE SITE OF PAIN**

50 COATED CAPLETS

500 MG



## BAYER HEADACHE

aspirin and caffeine tablet

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:0280-0064

Route of Administration

ORAL

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>ASPIRIN</b> (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	500 mg
<b>CAFFEINE</b> (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	32.5 mg

**Inactive Ingredients**

Ingredient Name	Strength
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>D&amp;C YELLOW NO. 10 ALUMINUM LAKE</b> (UNII: CQ3XH3DET6)	
<b>POWDERED CELLULOSE</b> (UNII: SMD1X3XO9M)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>D&amp;C RED NO. 30</b> (UNII: 2S42T2808B)	
<b>TRIACETIN</b> (UNII: XHX3C3X673)	
<b>SHELLAC</b> (UNII: 46N107B71O)	

**Product Characteristics**

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	Bayer;Headache
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0280-0064-01	1 in 1 CARTON	04/28/2021	
1		100 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0280-0064-02	1 in 1 CARTON	04/28/2021	
2		50 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	04/28/2021	

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

