

BAYER HEADACHE- aspirin and caffeine tablet
Bayer HealthCare LLC.

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



LOT/EXP label is to be reprinted.
No restriction on font size, style or color

LOT & EXP AREA

LOT/EXP
 3
 12843159218
 6

87374038

PS

Do not use if printed safety seal bearing "Bayer HealthCare" under cap is torn or missing.

Dist. by:
 Bayer HealthCare LLC
 Whippany, NJ 07981



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Bayer

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Drug Facts (continued)
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CLOSE ANGLE WAVE RULE

CLOSE ANGLE WAVE RULE

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
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	500 mg
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	32.5 mg

Inactive Ingredients

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

Product Characteristics

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

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)

