

BAYER HEADACHE- aspirin and 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.

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

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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PS

Drug Facts (continued)
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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 not final	part343	04/28/2021	

