

BAYER HEADACHE RELIEF- aspirin and caffeine capsule

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 RELIEF

Drug Facts

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

* nonsteroidal anti-inflammatory drug

Uses

for the temporary relief of

- headache
- muscle aches and pains

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
- asthma (wheezing)
- facial swelling
- 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

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

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) or www.bayeraspirin.com

PRINCIPAL DISPLAY PANEL - 50 Caplet Carton

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

BAYER[®]

HEADACHE

RELIEF

OFFICIAL SPONSOR

50 Coated Caplets

FAST, SAFE HEADACHE RELIEF

DUAL ACTION FORMULA



BAYER HEADACHE RELIEF

aspirin and caffeine capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0280-2635
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)	
Starch, corn (UNII: O8232NY3SJ)	
D&C red no. 30 (UNII: 2S42T2808B)	
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)	
Triacetin (UNII: XHX3C3X673)	

Product Characteristics

Color	WHITE	Score	no score
Shape	CAPSULE	Size	18mm
Flavor		Imprint Code	BAYER;HEADACHE
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0280-2635-50	1 in 1 CARTON		
1		50 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part343	06/01/2012	

Labeler - Bayer HealthCare LLC (785159372)

Establishment

Name	Address	ID/FEI	Business Operations
Bayer HealthCare LLC - Myerstown		072827066	MANUFACTURE(0280-2635)