

BAYER ASPIRIN EXTRA STRENGTH CAPLETS- bayer aspirin extra strength tablet
Bayer HealthCare LLC.

BAYER Aspirin Extra Strength Caplets

Drug Facts

Active ingredient (in each caplet)

Aspirin 500 mg (NSAID) ¹

¹ nonsteroidal anti-inflammatory drug

Pain reliever/fever reducer

Uses

temporarily relieves

- headache
- pain and fever of colds
- muscle pain
- menstrual pain
- toothache
- minor pain 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
 - fever lasts more than 3 days
 - 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 1 or 2 caplets every 4 to 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 #7 calcium lake, FD&C blue #2 aluminum lake, FD&C red #40 aluminum lake, hypromellose, powdered cellulose, propylene glycol, shellac, titanium dioxide, triacetin

Questions or comments?1-800-331-4536 (Mon – Fri 9AM – 5PM EST)

Carton 100 caplets



BAYER ASPIRIN EXTRA STRENGTH CAPLETS

bayer aspirin extra strength tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0280-2020
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	500 mg

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
STARCH, CORN (UNII: O8232NY3SJ)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
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	OVAL	Size	17mm
Flavor		Imprint Code	Extra;Strength;BAYER
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0280-2020-10	1 in 1 CARTON	12/23/2014	
1		100 in 1 BOTTLE, PLASTIC; 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	12/23/2014	

Labeler - Bayer HealthCare LLC. (112117283)

Establishment

Name	Address	ID/FEI	Business Operations
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Bayer HealthCare LLC Consumer Care		072827066	manufacture(0280-2020) , pack(0280-2020)
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Revised: 11/2023

Bayer HealthCare LLC.