BAYER ADVANCED ASPIRIN EXTRA STRENGTH- as pirin tablet Bayer HealthCare LLC, Consumer Care

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® Advanced Aspirin Extra Strength

Drug Facts

Active ingredient (in each tablet

Aspirin 500 mg $(NSAID)^1$

1 nonsteroidal anti-inflammatory drug

Purposes

Pain reliever/fever reducer

Uses

temporarily relieves

- headache
- muscle pain
- toothache
- menstrual pain
- pain and fever of colds
- 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

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
- you have a sodium-restricted diet

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 tablets every 4 to 6 hours, not to exceed 8 tablets in 24 hours
- children under 12 years: consult a doctor

Other information

- each tablet contains: sodium 72 mg
- store at room temperature. Avoid excessive heat and moisture.

• save carton for full directions and warnings

Inactive ingredients

carnauba wax, colloidal silicon dioxide, hypromellose, sodium carbonate, zinc stearate

Questions or comments?

1-800-331-4536 (Mon – Fri 9AM – 5PM EST) or www.BayerAdvancedAspirin.com

PRINCIPAL DISPLAY PANEL - 20 Tablet Carton

ADVANCED TABLET PACKS

ASPIRIN (NSAID) PAIN RELIEVER/FEVER REDUCER

BAYER[®]

ADVANCED

ASPIRIN

MICRO-PARTICLE

TECHNOLOGY

EXTRA

STRENGTH

FAST, SAFE PAIN RELIEF

500mg | 20 Coated Tablets

OFFICIAL SPONSOR

ASPIRIN (NSAID) PAIN RELIEVER/FEVER REDUCER DVANCE ASPIRIN



ADVANCED TABLET PACKS

ASPIRIN (NSAID) PAIN RELIEVER/FEVER REDUCER

VANCE

EXTRA STRENGTH

ASPIRIN

FAST, SAFE PAIN RELIEF





OFFICIAL SPONSOR



Do not use if packet is torn or open.

LOT & EXP AREA

EXPIRES



Drug Facts

Active Purposes ingredient (in each tablet)

Aspirin 500 mg

(NSAID)*..... ... Pain reliever/

fever reducer *nonsteroidal anti-inflammatory drug

Uses temporarily relieves

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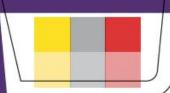
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goutdiabetesarthritis

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Made in Spain Bayer HealthCare LLC Consumer Care P.O. Box 1910 Morristown, NJ 07962-1910 USA







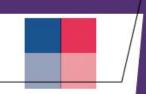
EXTRA STRENGTH

FAST, SAFE PAIN RELIEF

- Micro-Particle Technology for fast pain relief
- Extra Strength to work on your tough pains
- Safe and effective pain relief

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BAYER ADVANCED ASPIRIN EXTRA STRENGTH

aspirin tablet

Product Information

Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:0280-2610
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Aspirin (Aspirin)	Aspirin	500 mg	

Inactive Ingredients			
Ingredient Name	Strength		
Carnauba Wax	5.00 mg		
Silicon Dioxide	8.50 mg		
Hypromelloses	16.00 mg		
Sodium carbonate	25.00 mg		
Zinc stearate	4.61 mg		

Product Characteristics			
Color	WHITE	Score	no score
Shape	ROUND	Size	12mm
Flavor		Imprint Code	BA;500
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0280-2610-20	1 in 1 CARTON		
1		20 in 1 BOTTLE, PLASTIC		
2	NDC:0280-2610-40	1 in 1 CARTON		
2		40 in 1 BOTTLE, PLASTIC		
3	NDC:0280-2610-80	1 in 1 CARTON		
3		80 in 1 BOTTLE, PLASTIC		
4	NDC:0280-2610-01	507000 in 1 DRUM		
5	NDC:0280-2610-21	5 in 1 CARTON		
5		4 in 1 POUCH		
6	NDC:0280-2610-41	10 in 1 CARTON		
6		4 in 1 POUCH		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part343	12/0 1/20 12	

Revised: 1/2013