

ASPIRIN - aspirin tablet
Physicians Total Care, Inc.

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
325 mg Coated Tablet

Drug Facts

Active ingredient (in each tablet)

Aspirin 325 mg (NSAID)¹

¹ nonsteroidal anti-inflammatory drug

Purposes

Pain reliever/fever reducer

Uses

temporarily relieves

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

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 hours or 3 tablets every 6 hours, not to exceed 12 tablets in 24 hours
- children under 12 years: consult a doctor

Other information

- **each tablet contains:** sodium 47 mg

- store at room temperature. Avoid excessive heat and moisture. Keep desiccant and product in original bottle. Immediately close cap tightly after use.
- 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.bayeraspirin.com

PRINCIPAL DISPLAY PANEL - 325 mg Tablet

SEE NEW WARNINGS INFORMATION
NEW!



LOT & EXP

EXPIRES

ASPIRIN (NSAID) PAIN RELIEVER/FEVER REDUCER

BAYER

ADVANCED ASPIRIN

REGULAR STRENGTH

PS

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

F.P.O. 100% UPC TRUNCATED

3 12843 54578 6

Bayer HealthCare

Made in Germany

Bayer HealthCare LLC

Consumer Care

P.O. Box 1910

Morrisstown, NJ 07962-1910 USA

Bayer (reg'd), the Bayer Cross (reg'd) and Pro-Release are trademarks of Bayer.

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ASPIRIN (NSAID) PAIN RELIEVER/FEVER REDUCER

REGULAR STRENGTH

325 mg

FAST, SAFE PAIN RELIEF

ASPIRIN aspirin tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54868-1198(NDC:0280-2605)
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
Aspirin (UNII: R16CO5Y76E) (Aspirin - UNII:R16CO5Y76E)		Aspirin	325 mg
Inactive Ingredients			

Ingredient Name			Strength	
Carnauba Wax (UNII: R12CBM0EIZ)			5.00 mg	
Silicon Dioxide (UNII: ETJ7Z6XBU4)			8.50 mg	
Hypromelloses (UNII: 3NXW29V3WO)			16.00 mg	
Sodium carbonate (UNII: 45P3261C7T)			25.00 mg	
Zinc stearate (UNII: H92E6QA4FV)			4.61 mg	
Product Characteristics				
Color	WHITE	Score	no score	
Shape	ROUND	Size	10mm	
Flavor		Imprint Code	BA;325	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54868-1198-0	100 in 1 BOTTLE		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL		part343	02/27/1995	

Labeler - Physicians Total Care, Inc. (194123980)

Establishment

Name	Address	ID/FEI	Business Operations
Physicians Total Care, Inc.		19 4123980	relabel(54868-1198)

Revised: 4/2014

Physicians Total Care, Inc.