ASPIRIN NSAID- as pirin tablet A-S Medication Solutions

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.

Geri Care 44-249

Active ingredient (in each tablet)

Aspirin 325 mg (NSAID)*
*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/fever reducer

Uses

temporarily relieves:

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

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:

- facial swelling
- shock
- hives
- asthma (wheezing)

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
- 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
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug

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

- you have asthma
- 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

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

- 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
- an allergic reaction occurs. Seek medical help right away.
- ringing in the ears or loss of hearing occurs
- 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

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 (1-800-222-1222) 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: ask a doctor

Other information

- use by expiration date on package
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

Inactive ingredient

corn starch

Questions or comments?

1-800-540-3765

HOW SUPPLIED

Product: 50090-1617

NDC: 50090-1617-8 100 TABLET in a BOTTLE NDC: 50090-1617-4 20 TABLET in a BOTTLE

Aspirin



ASPIRIN NSAID

aspirin tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50090-1617(NDC:57896-901)
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
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics			
Color	WHITE	Score	no score

Shape	ROUND	Size	10 mm
Flavor		Imprint Code	44;249
Contains			

l	Packaging			
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 NDC:50090-1617-8	100 in 1 BOTTLE; Type 0: Not a Combination Product	0 1/12/20 15	
l	2 NDC:50090-1617-4	20 in 1 BOTTLE; Type 0: Not a Combination Product	0 1/12/20 15	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH NOT FINAL	part343	08/04/1993		

Labeler - A-S Medication Solutions (830016429)

Establishment				
Name	Address	ID/FEI	Business Operations	
A-S Medication Solutions		830016429	RELABEL(50090-1617), REPACK(50090-1617)	

Revised: 11/2017 A-S Medication Solutions