

**ASPIRIN- aspirin tablet, coated**  
**AAA Pharmaceutical, 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.*

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**RES - 1018 - 2019-0911**

***Drug Facts***

**Active ingredient (in each tablet)**

Aspirin 325 mg (NSAID) \*

\* nonsteroidal anti-inflammatory drug

**Purpose**

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

**Ask a doctor or pharmacist before use if you are** taking a prescription drug for:

- diabetes
- gout
- 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 for more than 10 days
- redness or swelling is present
- fever gets worse or lasts for more than 3 days
- new symptoms occur
- ringing in the ears or loss of hearing occurs

These could be signs of a serious condition.

**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 (1-800-222-1222).

**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**

- store between 20°-25°C (68°-77°F) in a dry place
- retain carton for complete product information and warnings

**Inactive ingredients**

corn starch, croscarmellose sodium, hypromellose, microcrystalline cellulose, mineral oil, titanium dioxide

**PRINCIPAL DISPLAY PANEL*****RESTORE u***

NDC 57344-018-11

†COMPARE TO THE ACTIVE INGREDIENT IN BAYER® ASPIRIN

REGULAR STRENGTH

Coated for Easy Swallowing

Aspirin

Pain Reliever / Fever Reducer

(NSAID)

Actual Size

100 COATED TABLETS - 325 MG EACH



**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 mg

**Inactive Ingredients**

Ingredient Name	Strength
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MINERAL OIL (UNII: T5L8T28FGP)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

**Product Characteristics**

Color	white	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	TCL;011
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57344-018-11	1 in 1 CARTON	10/01/2018	
1		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:57344-018-21	1 in 1 CARTON	09/01/2017	
2		50 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 not final	part343	09/01/2017	

**Labeler** - AAA Pharmaceutical, Inc. (181192162)

Revised: 9/2019

AAA Pharmaceutical, Inc.