

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

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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

INK AND COATING FREE  
FOR LOT AND  
EXPIRATION STAMPING



F101811RES\_R0

DO NOT USE IF IMPRINTED SEAL  
UNDER CAP IS BROKEN OR MISSING

This product is not manufactured or distributed by Bayer HealthCare LLC, distributor of Bayer Aspirin.

**Drug Facts**

**Active ingredient (in each tablet)** Purpose  
Aspirin 325 mg (NSAID)\* Pain reliever/fever reducer  
\*nonsteroidal anti-inflammatory drug

**Uses** temporarily relieves:  
 ■ headache ■ menstrual pain  
 ■ muscle pain ■ pain and fever of colds  
 ■ 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 ■ sneezing ■ 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  
 ■ 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

**Drug Facts (continued)**

■ 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 specifically 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 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

Distributed by:  
AAA Pharmaceutical, Inc.  
681 Main Street  
Lumberton, NJ 08048

**Drug Facts (continued)**  
**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

NDC 57344-018-11  
 †COMPARE TO THE ACTIVE INGREDIENT IN BAYER® ASPIRIN

**RESTORE<sup>U</sup>**

REGULAR STRENGTH  
**Aspirin**  
 Pain Reliever / Fever Reducer  
**(NSAID)**

Coated for Easy Swallowing

actual size **100 COATED TABLETS - 325 MG EACH**

NDC 57344-018-11  
 †COMPARE TO THE ACTIVE INGREDIENT IN BAYER® ASPIRIN

**RESTORE<sup>U</sup>**

REGULAR STRENGTH  
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**(NSAID)**

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actual size **100 COATED TABLETS - 325 MG EACH**

COATING FREE AREA

**ASPIRIN**

aspirin tablet, coated

**Product Information**

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:57344-018

**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 |
|--|----------|
| 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  |                      |                    |
| 3 | NDC:57344-018-19 | 300 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/22/2024           |                    |

**Marketing Information**

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M013                                     | 09/01/2017           |                    |

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