

ASPIRIN- aspirin tablet, delayed release
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.

Aspirin Tablets

Drug Facts

Active ingredient (in each tablet)

Aspirin 81 mg (NSAID¹)

¹ nonsteroidal anti-inflammatory drug

Purpose

Pain reliever

Uses

- temporarily relieves minor aches and pains

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 have ever had an allergic reaction to 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:

- 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 for more than 10 days
- redness or swelling is present
- 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 4 to 8 tablets every 4 hours; do not exceed 48 tablets in 24 hours
- children under 12 years: do not use unless directed by a doctor

Other information

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

Inactive ingredients

acetylated monoglycerides, anhydrous lactose, carnauba wax, colloidal silicon dioxide, croscarmellose sodium, FD&C red #40, FD&C yellow #6, hypromellose, hypromellose phthalate, iron oxide yellow, methacrylic acid copolymer, microcrystalline cellulose, mineral oil, polyethylene glycol, polysorbate 80, simethicone, sodium hydroxide, sodium lauryl sulfate, talc, titanium dioxide, triethyl citrate

Distributed by:

AAA Pharmaceutical, Inc.

681 Main Street
Lumberton, NJ 08048

PRINCIPAL DISPLAY PANEL - 180 Tablet Bottle Carton

RESTORE u

NDC 57344-146-01

†COMPARE TO THE ACTIVE
INGREDIENT IN ST JOSEPH®
SAFETY COATED ASPIRIN

***ADULT
LOW DOSE***

***Safety
Coated***

***Aspirin
Pain Reliever
(NSAID)***

81mg

180 ENTERIC COATED TABLETS - 81 mg each

COATING FREE AREA

Drug Facts

Active ingredient (in each tablet) Purpose
Aspirin 81 mg (NSAID).....Pain reliever
Nonsteroidal anti-inflammatory drug

Uses ■ temporarily relieves minor aches and pains

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.

Caution: 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 a 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 blood drug
■ take other drugs containing aspirin or nonsteroidal
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 have ever had an allergic reaction to
any other pain reliever/fever reducer

Ask a doctor before use if
■ you have a history of stomach problems, such as
heartburn
■ you have high blood pressure, heart disease,
liver cirrhosis, or kidney disease

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Drug Facts (continued)

Inactive ingredients acetylated
monoglycerate, anhydrous lactose, croscarmellose sodium, FD&C
color blue 2, croscarmellose sodium, FD&C
red #40, FD&C yellow #6, hypromellose, hypromellose
phthalate, iron oxide yellow, methacrylic acid copolymer,
microcrystalline cellulose, mineral oil, polyethylene
glycol, poly sorbate 80, simethicone, sodium hydroxide,
sodium lauryl sulfate, talc, titanium dioxide, triethyl citrate

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681 Main Street
Lumberton, NJ 08048
F1146 01 RES_PD

Drug Facts (continued)

■ you are taking a diuretic ■ you have asthma
Ask a doctor or pharmacist before use if you are
taking a prescription drug for:
■ gout ■ diabetes ■ or hives

Stop use and ask a doctor if

■ an allergic reaction occurs. Seek immediate help right away.
■ you experience any of the following signs of stomach
bleeding: ■ feel faint ■ vomit blood
■ have bloody or black stools
■ pain gets worse or lasts for more than 10 days
■ redness or swelling is present
■ new symptoms occur
■ ringing in the ears or loss of hearing occurs
These could be signs of a serious condition.

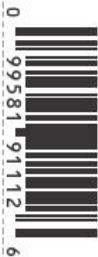
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Other information

■ store between 20°-25°C (68°-77°F) in a dry place
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INK AND COATING FREE
FOR LOT AND
EXPIRATION STAMPING



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

This product is not manufactured or distributed by St. Joseph Health
Products, LLC, distributor of St. Joseph Safety Coated Aspirin.

ASPIRIN

aspirin tablet, delayed release

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:57344-146

Route of Administration

ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	81 mg

Inactive Ingredients

Ingredient Name	Strength
DIACETYLATED MONO GLYCERIDES (UNII: 5Z17386USF)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
HYPROMELLOSE PHTHALATE (24 % PHTHALATE, 55 CST) (UNII: 87Y6436BKR)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics

Color	ORANGE (PEACH)	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	heart
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57344-146-01	1 in 1 CARTON		
1		180 in 1 BOTTLE, PLASTIC		
2	NDC:57344-146-02	1 in 1 CARTON		
2		300 in 1 BOTTLE, PLASTIC		
3	NDC:57344-146-03	1 in 1 CARTON		
3		100 in 1 BOTTLE, PLASTIC		
4	NDC:57344-146-04	2 in 1 CARTON		

4		180 in 1 BOTTLE, PLASTIC		
5	NDC:57344-146-05	300 in 1 BOTTLE, PLASTIC		
6	NDC:57344-146-06	500 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	12/15/20 12	

Labeler - AAA Pharmaceutical, Inc. (181192162)

Revised: 12/2012

AAA Pharmaceutical, Inc.