ASPIRIN- aspirin tablet, delayed release STRATEGIC SOURCING SERVICES LLC

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.

1146-FST-2023-0905

Drug Facts

Active ingredient (in each tablet)

Aspirin 81 mg (NSAID*)

* nonsteroidal anti-inflammatory drug

Purpose

Pain reliever

Uses

- temporarily relieves minor aches and pains
- ask your doctor about other uses for this product

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 useif 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 aretaking 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
- 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 not to exceed 48 tablets in 24 hours unless directed by a doctor
- 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 and warnings

Inactive ingredients

anhydrous lactose, carnauba wax, colloidal silicon dioxide, croscarmellose sodium, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, iron oxide ochre, methacrylic acid copolymer, microcrystalline cellulose, polysorbate 80, simethicone, sodium hydroxide, sodium lauryl sulfate, talc, triethyl citrate

Questions or comments?

Call 833-358-6431 Monday to Friday 9 am to 7 pm EST

PRINCIPAL DISPLAY PANEL

NDC 70677-1121-1

COMPARE TO ST.JOSEPH® LOW DOSE ASPIRIN ACTIVE INGREDIENT**

Foster & Thrive™

LOW DOSE

Aspirin 81 mg

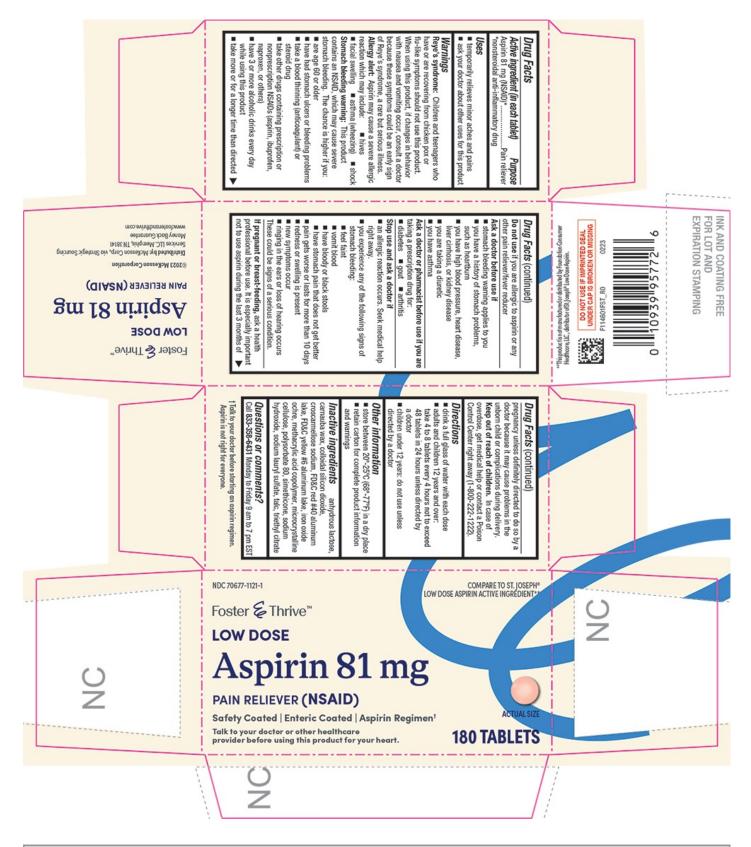
PAIN RELIEVER (NSAID)

Safety Coated | Enteric Coated | Aspirin Regiment

Talk to your doctor or other healthcare provider before using this product for your heart.

ACTUAL SIZE

180 TABLETS



ASPIRIN

aspirin tablet, delayed release

Product Information	Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70677-1121	
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	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)		
CARNAUBA WAX (UNII: R12CBM0EIZ)		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
ALUMINUM OXIDE (UNII: LMI26O6933)		
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		
FERRIC OXIDE YELLOW (UNII: EX43802MRT)		
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)		
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)		
POLYSORBATE 80 (UNII: 60ZP39ZG8H)		
DIMETHICONE (UNII: 92RU3N3Y10)		
SODIUM HYDROXIDE (UNII: 55X04QC32I)		
SODIUM LAURYL SULFATE (UNII: 368GB5141J)		
TALC (UNII: 7SEV7J4R1U)		
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)		

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

ı	Packaging			
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:70677- 1121-1	1 in 1 PACKAGE	09/05/2023	
	L	180 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	09/05/2023	

Labeler - STRATEGIC SOURCING SERVICES LLC (116956644)

Revised: 9/2023

STRATEGIC SOURCING SERVICES LLC