

# **ENTERIC COATED ASPIRIN REGULAR STRENGTH- aspirin tablet, delayed release**

**Strategic Sourcing Services LLC**

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**SMK - 1081B - 2019-0517**

## ***Drug Facts***

### **Active ingredient (in each tablet)**

Aspirin 325 mg (NSAID)\*

\* nonsteroidal anti-inflammatory drug

### **Purpose**

Pain reliever

### **Uses**

- for the temporary relief of minor aches and pains due to:
  - headache
  - muscle pain
  - toothache
  - menstrual pain
  - colds
  - minor pain of arthritis
- or as recommended by your doctor

### **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 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 to 2 tablets every 4 hours while

symptoms last; do not take more than 12 tablets in 24 hours unless directed by a doctor

- children under 12 years: ask 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, D&C yellow #10 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, methacrylic acid copolymer, microcrystalline cellulose, mineral oil, polysorbate 80, simethicone, sodium hydroxide, sodium lauryl sulfate, talc, titanium dioxide, triethyl citrate

### **PRINCIPAL DISPLAY PANEL**

sunmark®

COMPARE TO ECOTIN® REGULAR STRENGTH ACTIVE INGREDIENT†

NDC 70677-0071-1

enteric coated aspirin

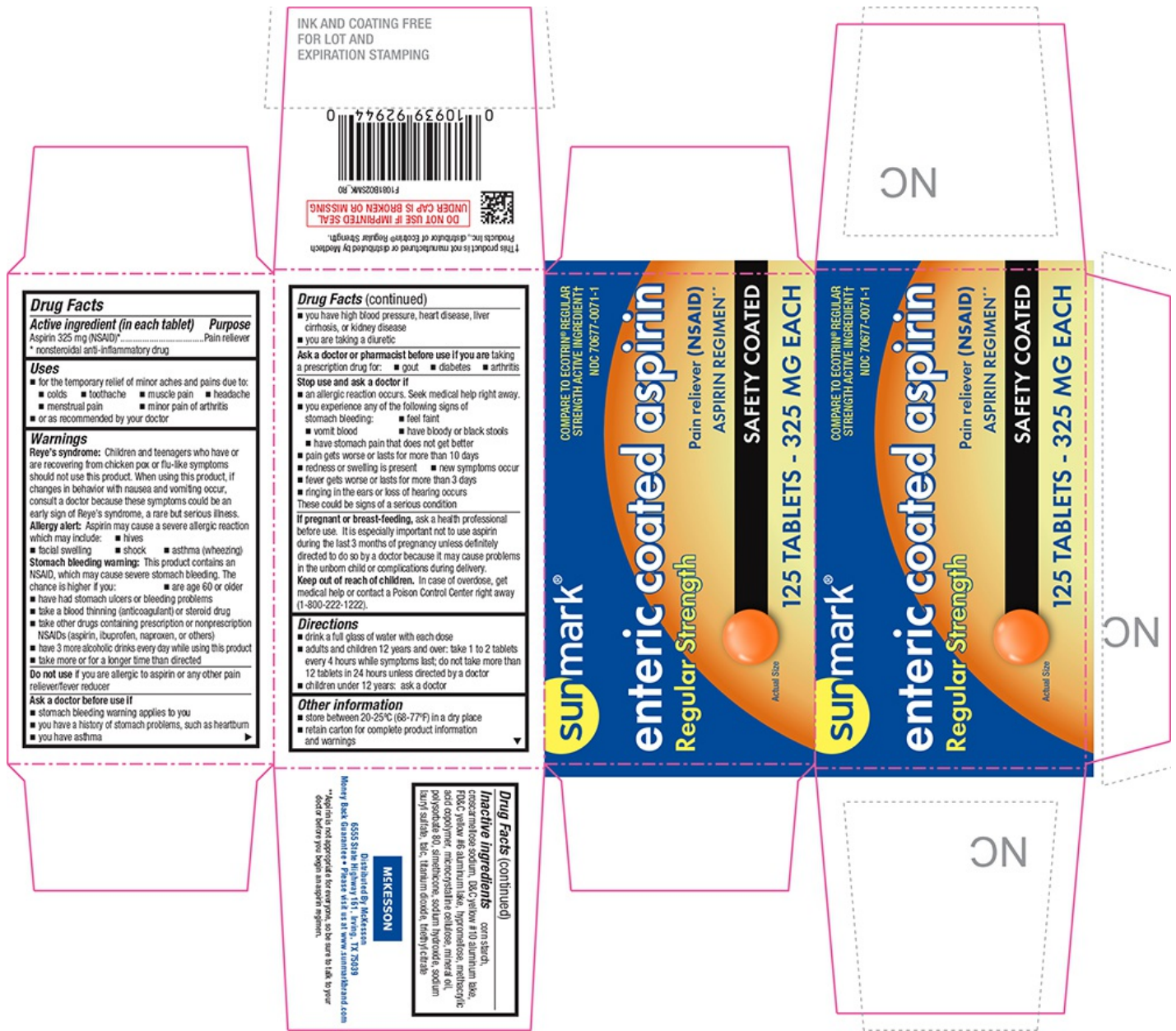
Regular Strength

Pain Reliever (NSAID)

ASPIRIN REGIMEN\*\*

SAFETY COATED

125 TABLETS - 325 MG EACH



## ENTERIC COATED ASPIRIN REGULAR STRENGTH

aspirin tablet, delayed release

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70677-0071
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ASPIRIN</b> (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 mg

### Inactive Ingredients

Ingredient Name	Strength

<b>STARCH, CORN</b> (UNII: O8232NY3SJ)
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)
<b>METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1)</b> (UNII: 74G4R6TH13)
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)
<b>TALC</b> (UNII: 7SEV7J4R1U)
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)
<b>TRIETHYL CITRATE</b> (UNII: 8Z96QXD6UM)

### Product Characteristics

<b>Color</b>	orange	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	T
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70677-0071-1	1 in 1 CARTON	05/17/2019	02/28/2025
1		1 in 1 PACKAGE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	05/17/2019	02/28/2025

**Labeler** - Strategic Sourcing Services LLC (116956644)