

**ASPIRIN- aspirin tablet, delayed release**  
**Harris Teeter**

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**HTE - 1146 - 2019-1010**

***Drug Facts***

**Active ingredient (in each tablet)**

Aspirin 81 mg (NSAID <sup>1</sup>)

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<sup>1</sup> 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

## **PRINCIPAL DISPLAY PANEL**

Harris Teeter

Adult Aspirin 81 mg

Compare to the Active Ingredient in St. Joseph(R) Safety Coated Aspirin

Lose Strength, 81 mg

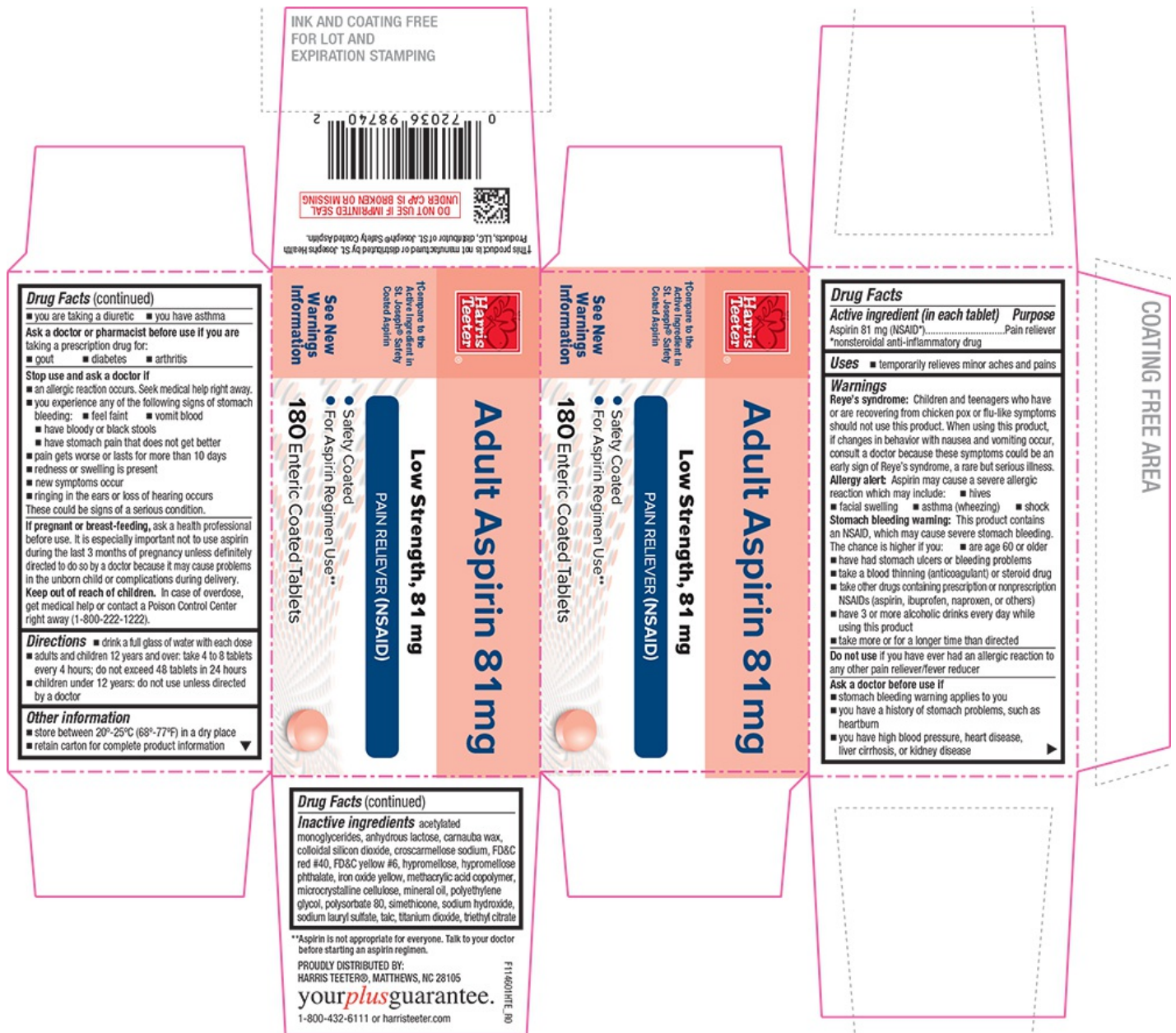
PAIN RELIEVER (NSAID)

Safety Coated

For Aspirin Regimen Use\*\*

See New Warnings Information

180 Enteric Coated Tablets



## ASPIRIN

aspirin tablet, delayed release

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72036-146
<b>Route of Administration</b>	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
<b>DIACETYLATED MONOGLYCERIDES</b> (UNII: 5Z17386USF)	
<b>ANHYDROUS LACTOSE</b> (UNII: 3SY5LH9PMK)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>HYPROMELLOSE PHTHALATE (24% PHTHALATE, 55 CST)</b> (UNII: 87Y6436BKR)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1)</b> (UNII: 74G4R6TH13)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<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 (PEACH)	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	7mm
<b>Flavor</b>		<b>Imprint Code</b>	heart
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72036-146-01	1 in 1 CARTON	10/06/2011	
1		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 Drug	M013	10/06/2011	

**Labeler** - Harris Teeter (047279351)