ASPIRIN- aspirin tablet
Bedrock Brands, LLC (ST. JOSEPH)

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.

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.

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
- shock
- 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
- have 3 or more alcoholic drinks every day while using this product
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- 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 have asthma
- you are taking a diuretic

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
- you experience any of the following signs of stomach bleeding:
  - feel faint
  - have bloody or black stools
  - vomit blood
  - have stomach pain that does not get better
  - an allergic reaction occurs. Seek medical help right away.
  - new symptoms occur
  - pain gets worse or lasts more than 10 days
  - redness or swelling is present
  - ringing in the ears or a loss of hearing occurs

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 of age and over**: take 4 to 8 tablets every 4 hours while symptoms persist
- do not exceed 48 tablets in 24 hours unless directed by a doctor
- **children under 12 years of age**: do not use unless directed by a doctor

Other information
- store at controlled room temperature 20°-25°C (68°-77°F)

Inactive ingredients

FD&C red #40, FD&C yellow #6, methacrylic acid copolymer, microcrystalline cellulose, pregelatinized starch, silicon dioxide, sodium bicarbonate, sodium lauryl sulfate, stearic acid, talc, triethyl citrate

Questions or comments?

Call toll free: **1 855 STJOE81**

Principal Display Panel

• ADULT ASPIRIN REGIMEN‡

LOW DOSE ASPIRIN

SAFETY COATED†

PAIN RELIEVER **(NSAID)**

81 mg

DOCTOR RECOMMENDED

Enteric Coated

Micro** Tablets

Dist. by: St. Josephs Health Products, LLC

Irvington, NY 10533

Find out more at stjosephaspirin.com

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

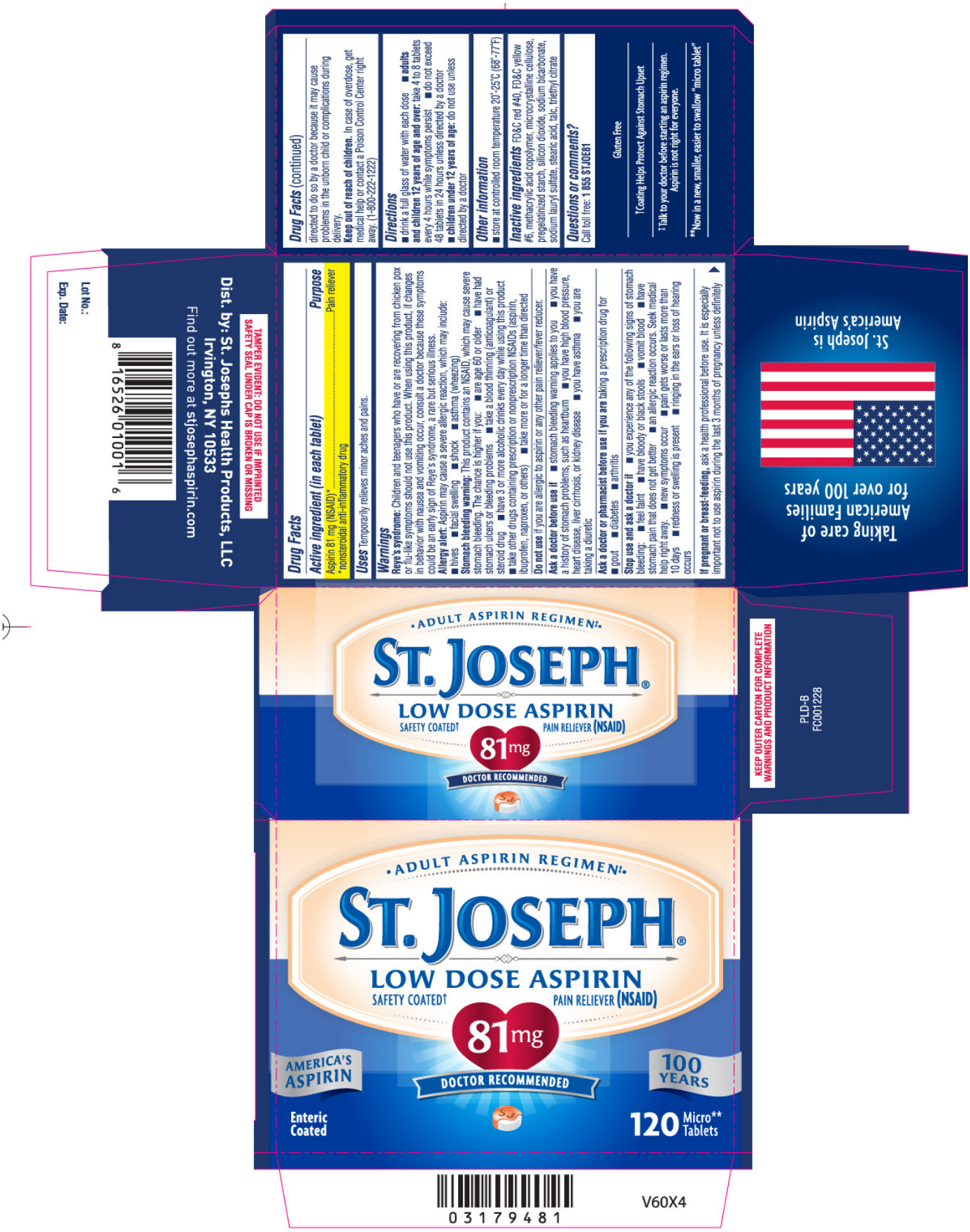
Gluten Free

†Coating Helps Protect Against Stomach Upset

‡Talk to your doctor before starting an aspirin regimen. Aspirin is not right for everyone.

**Now in a new, smaller, easier to swallow "micro tablet"

Product Label



St. Joseph Low Dose Aspirin Tablets

ASPIRIN

aspirin tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76000-231
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
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics

Color	WHITE (PEACH)	**Score**	no score
Shape	ROUND	**Size**	7mm
Flavor		**Imprint Code**	SJ
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76000-231-15	1 in 1 BOX		
1		150 in 1 BOTTLE, PLASTIC		
2	NDC:76000-231-36	1 in 1 BOX		
2		36 in 1 BOTTLE, PLASTIC		
3	NDC:76000-231-12	1 in 1 BOX		
3		120 in 1 BOTTLE, PLASTIC		
4	NDC:76000-231-20	1 in 1 BOX		
4		200 in 1 BOTTLE, PLASTIC		
5	NDC:76000-231-30	1 in 1 BOX		
5		300 in 1 BOTTLE, PLASTIC		
6	NDC:76000-231-65	1 in 1 BOX		
6		365 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part343	05/30/2014	

Labeler - Bedrock Brands, LLC (ST. JOSEPH) (829056162)

Revised: 7/2014 Bedrock Brands, LLC (ST. JOSEPH)