

## **ST. JOSEPH LOW DOSE ASPIRIN- aspirin tablet, film coated**

### **Foundation Consumer Healthcare**

*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.*

-----

## **St. Joseph Low Dose Aspirin**

### **Drug Facts**

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

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

---

1 nonsteroidal anti-inflammatory drug

#### **Purpose**

Pain reliever

#### **Uses**

- temporarily relieves minor aches and pain
- ask your doctor about other uses for St. Joseph Safety Coated 81 mg Aspirin

#### **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 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 gout, diabetes or 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 more than 10 days
- ringing in the ears or loss of hearing occurs
- redness or swelling is present
- new symptoms occur. 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 20 weeks or later in 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.

**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 not to 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 20-25°C (68-77°F)
- close cap tightly after use

## **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 **1-855-785-6381** weekdays 9 AM to 5 PM EST

Dist. by: Foundation Consumer Healthcare, LLC.  
Pittsburgh, PA 15205

## **PRINCIPAL DISPLAY PANEL - 36 Tablet Bottle Box**

•ADULT ASPIRIN REGIMENT†•

ST. JOSEPH®

LOW DOSE ASPIRIN  
SAFETY COATED  
PAIN RELIEVER (NSAID)

81mg

AMERICA'S  
ASPIRIN

100  
YEARS

DOCTOR RECOMMENDED

Enteric  
Coated

36  
Coated  
Tablets

No Print/No Varnish Lot & Expiry Area



Dist. by: Foundation Consumer Healthcare, LLC, Pittsburgh, PA 15212 ©2022 sfjosephaspirin.com

B-0603-750-07R REV-A

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Drug Facts Active ingredient (in each tablet) Aspirin 81 mg (NSAID) Nonsteroidal anti-inflammatory drug

Uses Temporarily relieves minor aches and pain ask your doctor about other uses for St. Joseph Safety Coated 81 mg Aspirin

Warnings Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, it 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 are allergic to aspirin or any other pain reliever/fever reducer

Drug Facts (continued) 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; you are taking a diuretic; you have asthma; you are taking a diuretic; you are taking a prescription drug for gout, diabetes or arthritis; you experience any of the following signs or symptoms: stomach bleeding; vomit blood; have bloody or black stools; have stomach pain that does not get better; pain gets worse or lasts more than 10 days; ringing in the ears or loss of hearing occurs; redness or swelling is present; new symptoms occur. 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 at 20 weeks or later in pregnancy unless specifically directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery. In case of overdose, get medical help or contact a Poison Control Center right away.

Drug Facts (continued) 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 not to 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 20-25°C (68-77°F) close cap tightly after use

Inactive ingredients colloidal anhydrous silica, FD&C red #40, FD&C yellow #6, hypromellose, methacrylic acid-ethyl acrylate copolymer, microcrystalline cellulose, polydextrose, polyethylene glycol, pregelatinized starch, shellac wax, simethicone, sodium bicarbonate, sodium lauryl sulfate, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments? Call 1-855-785-6381 weekdays 9 AM to 5 PM EST

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

ADULT ASPIRIN REGIMEN. ST. JOSEPH. LOW DOSE ASPIRIN SAFETY COATED PAIN RELIEVER (NSAID) 81mg DOCTOR RECOMMENDED 100 YEARS 36 Coated Tablets

ADULT ASPIRIN REGIMEN. ST. JOSEPH. LOW DOSE ASPIRIN SAFETY COATED PAIN RELIEVER (NSAID) 81mg DOCTOR RECOMMENDED 100 YEARS 36 Coated Tablets

LEBGG775S2

# ST. JOSEPH LOW DOSE ASPIRIN

aspirin tablet, film coated

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69536-181
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
Aspirin (UNII: R16CO5Y76E) (Aspirin - UNII:R16CO5Y76E)	Aspirin	81 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
METHACRYLIC ACID (UNII: 1CS02G8656)	
MICROCRYSTALLINE CELLULOSE (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

<b>Color</b>	WHITE (PEACH)	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	7mm
<b>Flavor</b>		<b>Imprint Code</b>	SJ
<b>Contains</b>			

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:69536-181-15	1 in 1 BOX	02/17/2017	
1		150 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:69536-181-36	1 in 1 BOX	02/17/2017	
2		36 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:69536-181-12	1 in 1 BOX	02/17/2017	
3		120 in 1 BOTTLE; Type 0: Not a Combination Product		

3		Product		
4	NDC:69536-181-20	1 in 1 BOX	02/17/2017	
4		200 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:69536-181-54	1 in 1 BOX	02/17/2017	05/01/2018
5		54 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:69536-181-65	1 in 1 BOX	02/17/2017	
6		365 in 1 BOTTLE; 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	02/17/2017	

**Labeler** - Foundation Consumer Healthcare (079675882)

Revised: 12/2022

Foundation Consumer Healthcare