

**ASPIRIN REGIMEN- aspirin tablet, delayed release**  
**Cardinal Health 110, LLC. DBA Leader**

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**Leader 44-645-Aspirin Regimen**

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

Aspirin 81 mg (NSAID)\*

\*nonsteroidal anti-inflammatory drug

***Purpose***

Pain reliever

***Uses***

for the temporary relief of minor aches and pains or as recommended by your doctor.  
**Because of its delayed action, this product will not provide fast relief of headaches or other symptoms needing immediate relief.**

***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

- take a blood thinning (anticoagulant) or steroid drug
- are age 60 or older
- take more or for a longer time than directed
- have 3 or more alcoholic drinks every day while using this product
- have had stomach ulcers or bleeding problems
- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]

**Do not use**

- if you are allergic to aspirin or any other pain reliever/fever reducer
- if you have ever had an allergic reaction to this product or any of its ingredients

**Ask a doctor before use if**

- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you are taking a diuretic
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- 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:
  - vomit blood
  - have bloody or black stools
  - feel faint
  - have stomach pain that does not get better
- ringing in the ears or a loss of hearing occurs
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- 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 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***

- **do not take more than directed**
- 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 at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

## ***Inactive ingredients***

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

## ***Questions or comments?***

**1-800-426-9391**

## ***Principal display panel***

LEADER™

NDC 70000-0604-2

Low Dose | Safety Coated

**Aspirin Regimen\*\***

Delayed Release, 81 mg | Pain Reliever **(NSAID)**

COMPARE TO

ST. JOSEPH®

LOW DOSE ASPIRIN

active ingredient†

100% Money Back Guarantee

36 ENTERIC COATED

TABLETS

Actual Size

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

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

†This product is not manufactured or distributed by Foundation  
Consumer Healthcare, LLC, owner of the registered trademark  
St. Joseph® Low Dose Aspirin.

50844 REV0122A64507

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[www.myleader.com](http://www.myleader.com) 1-800-200-6313

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lot no. & exp. date

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St Joseph Low Dose Aspirin  
Consumer Healthcare, LLC owner of the registered trademark  
This product is not manufactured or distributed by Foundation

**\*\*Talk to your doctor or other healthcare provider before using this product for your heart.**  
CIN 5777685 REV. 5/22  
TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

NDC 70000-0604-1

**LEADER**

Low Dose | Safety Coated  
**Aspirin Regimen**<sup>™</sup>  
Delayed Release, 81 mg | Pain Reliever (NSAID)

36 ENTERIC COATED TABLETS

Actual Size

COMPARE TO ST. JOSEPH<sup>®</sup> LOW DOSE ASPIRIN active ingredient<sup>†</sup>

100% Money Back Guarantee

**Drug Facts (continued)**  
1-800-426-9391  
*Questions or comments?*

**Drug Facts** (continued)  
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**Drug Facts (continued)**

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 definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.  
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**Drug Facts (continued)**

- have had stomach ulcers or bleeding problems
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)

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Leader 44-645

**ASPIRIN REGIMEN**  
aspirin tablet, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0604
Route of Administration	ORAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

Ingredient Name	Strength
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<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>METHACRYLIC ACID</b> (UNII: 1CS02G8656)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYDEXTROSE</b> (UNII: VH2XOU12IE)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>SHELLAC</b> (UNII: 46N107B71O)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TRIACETIN</b> (UNII: XHX3C3X673)	
<b>TRIETHYL CITRATE</b> (UNII: 8Z96QXD6UM)	

**Product Characteristics**

<b>Color</b>	pink	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	6mm
<b>Flavor</b>		<b>Imprint Code</b>	L
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0604-1	1 in 1 CARTON	06/01/2022	
1		36 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:70000-0604-2	1 in 1 CARTON	06/01/2022	
2		120 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
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OTC Monograph Drug	M013	06/01/2022	
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**Labeler** - Cardinal Health 110, LLC. DBA Leader (063997360)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(70000-0604)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(70000-0604)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(70000-0604)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	manufacture(70000-0604)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(70000-0604)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(70000-0604)

Revised: 9/2023

Cardinal Health 110, LLC. DBA Leader