

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

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**Leader 44-600A 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

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

**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:
  - have bloody or black stools
  - feel faint
  - have stomach pain that does not get better
  - vomit blood
- 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)

- use by expiration date on package

### ***Inactive ingredients***

corn starch, D&C yellow #10, FD&C yellow #6, hypromellose, methacrylic acid, microcrystalline cellulose, polydextrose, polyethylene glycol, shellac wax, silica, simethicone, sodium bicarbonate, sodium lauryl sulfate, talc, titanium dioxide, triacetin, triethyl citrate

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

**1-800-426-9391**

### ***Principal display panel***

LEADER™

NDC 70000-0603-3

Low Dose | Safety Coated

### **Aspirin Regimen\*\***

Tablets, 81 mg  
Pain Reliever **(NSAID)**

\*\*Talk to Your Doctor or Other  
Healthcare Provider before Using  
This Product for Your Heart.

**COMPARE TO  
BAYER® LOW  
DOSE ASPIRIN**  
active ingredient†

100% Money  
Back Guarantee

Actual Size

**300**  
ENTERIC COATED  
TABLETS

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

†This product is not manufactured or distributed by Bayer AG, owner of the registered trademark Bayer® Low Dose Aspirin.

50844 ORG012260017

DIST. BY CAH DUBLIN OH, 43017  
www.myleader.com 1-800-200-6313  
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✓ 100%  
**Money Back  
 Guarantee**  
 Return to place of purchase.

NDC 70000-0603-3

**Low Dose | Safety Coated**

**Aspirin Regimen\*\***

Tablets, 81 mg  
 Pain Reliever (NSAID)

**LEADER**

**300** ENTERIC COATED TABLETS

Actual Size

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**Questions or comments?** 1-800-426-9391

STOP PEELING

**Drug Facts (continued)**

■ if you have ever had an allergic reaction to this product or any of its ingredients

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**Ask a doctor or pharmacist before use if you are taking a prescription drug for** ■ gout ■ diabetes ■ arthritis

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**100% Money Back Guarantee**

Return to place of purchase.

**PEEL HERE FOR MORE DRUG FACTS**

**CIN 5777669 REV. 5/22**

0 96295 14199 3

www.mylab.com 1-800-200-6333

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This product is not manufactured or distributed by Bayer AG, owner of the registered trademark Bayer® Low Dose Aspirin. 50644 0RG01260017

**Leader 600A**

<b>ASPIRIN REGIMEN</b>			
aspirin tablet, delayed release			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70000-0603
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
	ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	81 mg
<b>Inactive Ingredients</b>			
	<b>Ingredient Name</b>		<b>Strength</b>

<b>STARCH, CORN</b> (UNII: O8232NY3SJ)
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)
<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: 3WQ0SDW1A)
<b>SHELLAC</b> (UNII: 46N107B71O)
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)
<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>	yellow	<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:70000-0603-3	300 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/05/2022	
2	NDC:70000-0603-2	1 in 1 CARTON	05/05/2022	
2		120 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:70000-0603-1	1 in 1 CARTON	05/05/2022	
3		32 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	05/05/2022	

**Labeler** - Cardinal Health 110, LLC. DBA Leader (063997360)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(70000-0603)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(70000-0603)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	manufacture(70000-0603) , pack(70000-0603)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(70000-0603)

Revised: 5/2024

Cardinal Health 110, LLC. DBA Leader