**ADULT ASPIRIN REGIMEN- aspirin tablet, film coated**
**Cardinal Health 110, LLC. DBA Leader**

*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.*

---

**Leader 44-600A Adult-Delisted**

### *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
- shock
- facial swelling
- asthma (wheezing)

**Stomach bleeding warning:** This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you
- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]
- take more or for a longer time than directed
- 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
- are age 60 or older

**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 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:
  - vomit blood
  - feel faint
  - have bloody or black stools
  - 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
- 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 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 (1-800-222-1222) right away.

***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 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 25ºC (77ºF); excursions permitted between 15º-30ºC (59º-86ºF)
- see end flap for expiration date and lot number

### *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 70000-0178-3

Low Dose | Safety Coated

**Adult Aspirin Regimen****
Tablets, 81 mg | Pain Reliever **(NSAID)**

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

**120**
ENTERIC COATED
TABLETS

Actual Size

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

100% Money Back Guarantee

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

**CIN 5528153 REV. 6/19**

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

50844 ORG031860032

DISTRIBUTED BY CARDINAL HEALTH
DUBLIN, OH 43017
www.myleader.com 1-800-200-6313



100% Money Back Guarantee

Return to place of purchase.


**Leader 44-600A**

## ADULT ASPIRIN REGIMEN

aspirin tablet, film coated

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:70000-0178 |
| **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 |
|---|---|
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **D&C YELLOW NO. 10** (UNII: 35SW5USQ3G) | |
| **FD&C YELLOW NO. 6** (UNII: H77VEI93A8) | |
| **HYPROMELLOSE, UNSPECIFIED** (UNII: 3NXW29V3WO) | |
| **METHACRYLIC ACID** (UNII: 1CS02G8656) | |
| **MICROCRYSTALLINE CELLULOSE** (UNII: OP1R32D61U) | |
| **POLYDEXTROSE** (UNII: VH2XOU12IE) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **SODIUM BICARBONATE** (UNII: 8MDF5V39QO) | |
| **SODIUM LAURYL SULFATE** (UNII: 368GB5141J) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **TRIACETIN** (UNII: XHX3C3X673) | |
| **TRIETHYL CITRATE** (UNII: 8Z96QXD6UM) | |
| **SHELLAC** (UNII: 46N107B71O) | |
| **DIMETHICONE** (UNII: 92RU3N3Y1O) | |
| **WATER** (UNII: 059QF0KO0R) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | yellow | **Score** | no score |
| **Shape** | ROUND | **Size** | 6mm |
| **Flavor** | | **Imprint Code** | L |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:70000-0178-2 | 300 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 05/01/2011 | 06/22/2024 |
| **2** | NDC:70000-0178-3 | 1 in 1 CARTON | 05/01/2011 | 06/22/2024 |
| **2** | | 120 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |
| **3** | NDC:70000-0178-1 | 1 in 1 CARTON | 05/01/2011 | 06/22/2024 |
| **3** | | 32 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 | 05/01/2011 | 06/22/2024 |

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

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| LNK International, Inc. | | 038154464 | pack(70000-0178) |

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| LNK International, Inc. | | 868734088 | manufacture(70000-0178) , pack(70000-0178) |

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| LNK International, Inc. | | 967626305 | pack(70000-0178) |

Revised: 8/2022 Cardinal Health 110, LLC. DBA Leader