

**LEADER ASPIRIN- aspirin tablet, chewable**  
**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.*

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**Cardinal Health Aspirin Drug Facts**

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

Aspirin 81 mg (NSAID\*)

\*nonsteroidal anti-inflammatory drug

**Purpose**

Pain reliever

**Uses**

for the temporary relief of 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
- 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 have ever had an allergic reaction to any other pain reliever/fever reducer
- for at least 7 days after tonsillectomy or oral surgery unless directed by a doctor

### **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:
  - 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
  - fever gets worse or lasts more than 3 days
  - redness or swelling is present
  - new symptoms occur
  - ringing in the ears or a loss of hearing occurs

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 (1-800-222-1222).

### **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: consult a doctor

### **Other information**

- store at 20-25°C (68-77°F)

### **Inactive ingredients**

corn starch, dextrose excipient, FD&C yellow no. 6 aluminum lake, flavors, saccharin sodium

### **Questions or comments?**

**1-800-719-9260**

### **Principal Display Panel**

LEADER™

Chewable Aspirin

81 mg Tablets | Pain Reliever (NSAID)

COMPARE TO BAYER® CHEWABLE LOW DOSE ASPIRIN

active ingredient

Orange Flavored

Low Dose Aspirin Regimen

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

Actual Size

100% Money Back Guarantee

36 TABLETS

SEE NEW WARNING

46768 E9 C9

DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING

CIN 5463765 REV. 5/22

**Drug Facts**

**Active ingredient (in each chewable tablet)**  
Aspirin 81 mg (NSAID)\*

**Purpose**  
Pain reliever  
\*nonsteroidal anti-inflammatory drug

**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)
  - stomach bleeding
  - 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

**Drug Facts (continued)**

Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer for at least 7 days after tonsillectomy or oral surgery unless directed by a doctor

**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
- you are taking a prescription drug for gout, diabetes, or arthritis

**Ask a doctor or pharmacist before use if you are taking a prescription drug for:**

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

**Drug Facts (continued)**

**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 and over: take 4 to 8 chewable tablets every 4 hours not to exceed 48 tablets in 24 hours unless directed by a doctor
- children under 12 years: consult a doctor

**Other information**

- store at 20-25°C (68-77°F)

NDC 70000-0420-1

**Chewable**

# Aspirin

81 mg Tablets | Pain Reliever (NSAID)

Orange Flavored  
Low Dose Aspirin Regimen  
Talk to Your Doctor or Other Healthcare Provider before Using This Product for Your Heart



Actual Size

**36 TABLETS** SEE NEW WARNING

**LEADER**

COMPARE TO BAYER® CHEWABLE LOW DOSE ASPIRIN active ingredient\*\*

100% Money Back Guarantee

**Drug Facts (continued)**  
Inactive ingredients: corn starch, dextrose exceptant, FD&C yellow no. 6 aluminum lake, flavors, saccharin sodium

**Questions or comments?**  
1-800-719-9280

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DISTRIBUÍD BY CARDINAL HEALTH, DUBLIN, OH 43017  
www.mylender.com 1-800-2-00-6513

**LEADER ASPIRIN**  
aspirin tablet, chewable

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70000-0420
<b>Route of Administration</b>	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>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	

### Product Characteristics

<b>Color</b>	ORANGE	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	8mm
<b>Flavor</b>	ORANGE	<b>Imprint Code</b>	L467
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0420-1	1 in 1 CARTON	08/13/2018	
1		36 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:70000-0420-2	3 in 1 CARTON	08/13/2018	11/30/2021
2		36 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	08/13/2018	

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