## LEADER EXTRA STRENGTH EFFERVESCENT ANTACID AND PAIN RELIEVERaspirin, citric acid, sodium bicarbonate tablet, effervescent Cardinal Health

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## Leader Extra Strength Effervescent Antacid & Pain Reliever

## **Active ingredients**

(in each effervescent tablet)

Anhydrous citric acid 1000 mg

Aspirin 500 mg (NSAID)\*

Sodium bicarbonate (heat-treated) 1985 mg

## **Purpose**

## (in each effervescent tablet)

#### Uses

Uses for the temporary relief of

- heartburn, acid indigestion and sour stomach when accompanied by headache or body aches and pains
- upset stomach with headache from overindulgence in food or drink
- headache, body aches and pain alone

## **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

<sup>\*</sup>Nonsteroidal anti-inflammatory drug

stomach ulcers or bleeding problems **t**ake 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
- 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 ■ you have a sodium-restricted diet

## Ask a doctor or pharmacist before use if you are

- presently taking a prescription drug. Antacids may interact with certain prescription drugs.
- taking a prescription drug for anticoagulation (thinning the blood), diabetes, gout or arthritis

## When using this product

**When using this product** do not take more than 8 tablets (adults) or 4 tablets (60 years and over) in a 24-hour period or use the maximum dosage for more than 2 weeks, except under the advice and supervision of a physician.

## Stop use and ask a doctor if

**Stop use and ask a doctor if** ■ 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
- an allergic reaction occurs. Seek medical help right away.
- pain lasts for more than 10 days or gets worse
- new symptoms occur
- redness or swelling is present
- ringing in the ears or a loss of hearing occurs

## If pregnant or breast-feeding

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**

- do not exceed recommended dosage
- to avoid serious injury, completely dissolve tablets in 4 oz. of water before taking adults and children 12 years and over (up to 60 years of age): 2 tablets every 4 hours do not exceed 8 tablets in 24 hours

60 years and over: 2 tablets every 4 hours - do not exceed 4 tablets in 24 hours Children under 12 years: consult a doctor

#### Other information

- each tablet contains: sodium 575 mg
- store at room temperature (59º-86ºF)

## **Inactive ingredients**

flavor

Questions or comments?

1-888-228-6937

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



# LEADER EXTRA STRENGTH EFFERVESCENT ANTACID AND PAIN RELIEVER

aspirin, citric acid, sodium bicarbonate tablet, effervescent

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0574	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO) (BICARBONATE ION - UNII:HN1Z RA3Q20)	SODIUM BICARBONATE	1985 mg	
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	500 mg	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL) (ANHYDROUS CITRIC ACID - UNII: XF417D3PSL)	ANHYDROUS CITRIC ACID	1000 mg	

Inactive Ingredients			
	Ingredient Name	Strength	
<b>LEMON</b> (UNII: 24RS0A9880)			

Product Characteristics			
Color	white	Score	no score
Shape	ROUND	Size	25mm
Flavor		Imprint Code	PXS
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:70000- 0574-1	18 in 1 CARTON	06/25/2021		
1		2 in 1 POUCH; 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	06/25/2021	

## Labeler - Cardinal Health (063997360)

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