

**LEADER EXTRA STRENGTH EFFERVESCENT ANTACID AND PAIN RELIEVER-
aspirin, citric acid, sodium bicarbonate tablet, effervescent
Cardinal Health**

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 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

*Nonsteroidal anti-inflammatory drug

Purpose

(in each effervescent tablet)

Anhydrous citric acid 1000 mg.....Antacid

Aspirin 500 mg **(NSAID)***.....Pain Reliever

Sodium bicarbonate (heat-treated) 1985 mg.....Antacid

*Nonsteroidal anti-inflammatory drug

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 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 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 (59°-86°F)

Inactive ingredients

flavor

Questions or comments?

1-888-228-6937

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



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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
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (BICARBONATE ION - UNII:HN1ZRA3Q20)	SODIUM BICARBONATE	1985 mg
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	500 mg
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	1000 mg

Inactive Ingredients

Ingredient Name	Strength
LEMONE (UNII: 24RS0A988O)	

Product Characteristics

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

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 final	part343	06/25/2021	

Labeler - Cardinal Health (063997360)