

LEADER EFFERVESCENT ANTACID AND PAIN RELIEF- 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 Effervescent Antacid & Pain Relief

Purpose

Anhydrous citric acid 1000mg.....Antacid
Aspirin 325mg.....Pain reliever
Sodium bicarbonate 1916mg.....Antacid

Active Ingredients

(in each effervescent tablet)

Anhydrous citric acid 1000mg
Aspirin 325mg **(NSAID)***
Sodium bicarbonate 1916mg

*Nonsteroidal anti-inflammatory drug

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 ■ pain alone (headaches or body 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 a nonsteroidal anti-inflammatory drug (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 ■ if you are allergic to aspirin ■ if overly full from food or drink. Ask a doctor if severe stomach pain occurs after taking this product.

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 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

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 10 days

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,

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 right away. 1-800-222-1222

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 or as directed by a doctor
- do not exceed 8 tablets in 24 hours
- 60 years and over: 2 tablets every 4 hours or as directed by a doctor
- do not exceed 4 tablets in 24 hours
- Children under 12 years: consult a doctor

Other information

- **each tablet contains:** sodium 524 mg
- store at room temperature (59°-86°F)

Inactive ingredients

- none

Questions or comments?

Call **1-888-228-6931**

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



LEADER EFFERVESCENT ANTACID AND PAIN RELIEF

aspirin, citric acid, sodium bicarbonate tablet, effervescent

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0421
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 mg
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (BICARBONATE ION - UNII:HN1Z RA3Q20)	SODIUM BICARBONATE	1916 mg
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	1000 mg

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	25mm
Flavor		Imprint Code	L421
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0421-1	18 in 1 CARTON	04/10/2019	
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	04/10/2019	12/31/2024

Labeler - Cardinal Health (063997360)

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