

EFFERVESCENT ANTACID AND PAIN RELIEF - aspirin, sodium bicarbonate, citric acid tablet, effervescent Cardinal Health Inc.

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.

Drug Facts

Active Ingredients (in each effervescent tablet)	Purpose
Aspirin 325mg NSAID*	Pain Reliever
Citric Acid 1000 mg	Antacid
Sodium Bicarbonate (heat-treated) 1916 mg	Antacid

*Nonsteroidal anti-inflammatory drug

Warnings

Reye's syndrome: Children and teenagers should not use this drug for chicken pox or flu symptoms before a doctor is consulted about Reye's syndrome, a rare but serious illness reported to be associated with aspirin.

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.

Alcohol warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take aspirin or other pain relievers/fever reducers. Aspirin may cause stomach bleeding.

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)

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

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

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.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

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.

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

When using this product do not take more than 8 tablets (adults) and 4 tablets (60 years and over) in a 24-hour period or use the maximum dosage for more than 10 days.

Fast Relief of: Indigestion, Upset stomach, Heartburn with headache, Body Aches and Pains.

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 year and over

2 tablets every 4 hours
do not exceed 4 tablets in 24 hours

There are no inactive ingredients.



EFFERVESCENT ANTACID AND PAIN RELIEF

aspirin, sodium bicarbonate, citric acid tablet, effervescent

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37205-196
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (BICARBONATE ION - UNII:HN1ZRA3Q20)	BICARBONATE ION	19.16 mg	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	1000 mg	
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 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:37205-196-68	36 in 1 CARTON		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	12/01/2006	

Labeler - Cardinal Health Inc. (097537435)**Registrant** - United Exchange Corporation (840130579)**Establishment**

Name	Address	ID/FEI	Business Operations
Tower Laboratories Ltd		869024500	manufacture(37205-196)

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Cardinal Health Inc.