

**ALKA-SELTZER EXTRA STRENGTH- anhydrous citric acid, sodium bicarbonate, and aspirin granule, effervescent**  
**Bayer HealthCare LLC.**

*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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**Alka-Seltzer Extra Strength**

**Drug Facts**

<b>Active ingredients (in each tablet)</b>	<b>Purpose</b>
Anhydrous citric acid 1000 mg	Antacid
Aspirin 500 mg	Analgesic
Sodium bicarbonate (heat-treated) 1985 mg	Antacid

**Uses**

for the temporary relief of:

- heartburn, acid indigestion, and sour stomach when accompanied with 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 (blood thinning), diabetes, gout, or arthritis

**When using this product do not exceed recommended dosage****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
    - symptoms get worse or last more than 10 days
    - redness or swelling is present
    - ringing in the ears or a loss of hearing occurs
    - new symptoms occur

**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.

**Directions**

- fully dissolve 2 tablets in 4 ounces of water before taking

adults and children 12 years and over	2 tablets every 6 hours, or as directed by a doctor	do not exceed 7 tablets in 24 hours
adults 60 years and over	2 tablets every 6 hours, or as directed by a doctor	do not exceed 3 tablets in 24 hours
children under 12 years	consult a doctor	

**Other information**

- **each tablet contains:** sodium 588 mg
- store at room temperature. Avoid excessive heat.
- Alka-Seltzer Extra Strength in water contains principally the antacid sodium citrate and the analgesic sodium acetylsalicylate

**Inactive ingredients**

flavor

**Questions or comments?**

**1-800-986-0369** (Mon - Fri 9AM - 5PM EST)

**PRINCIPAL DISPLAY PANEL - 24 Tablets Carton**

**Alka-**

**Seltzer** ®

**ANTACID & PAIN RELIEF MEDICINE**

**FAST**

**RELIEF**

**OF:**

**Acid Indigestion**

**Upset Stomach**

**Heartburn with**

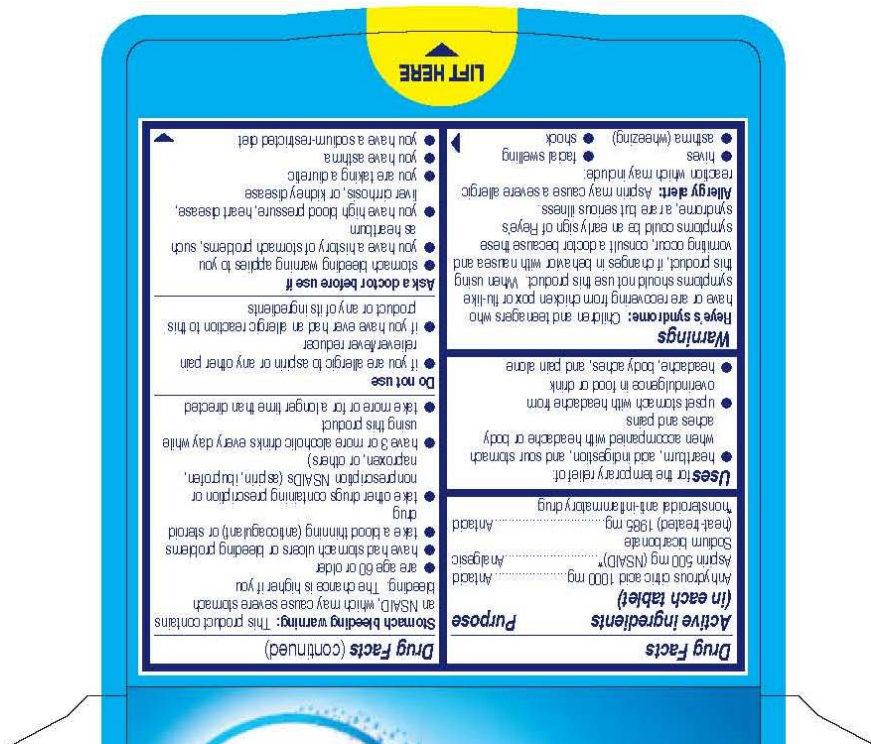
**Headache**

**Body Aches**

**XTRA**

**STRENGTH**

**24 EFFERVESCENT TABLETS**



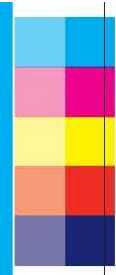
14

PS



**EXTRA STRENGTH**

24 EFFERVESCENT TABLETS  
Do not use if pouch is torn or open.

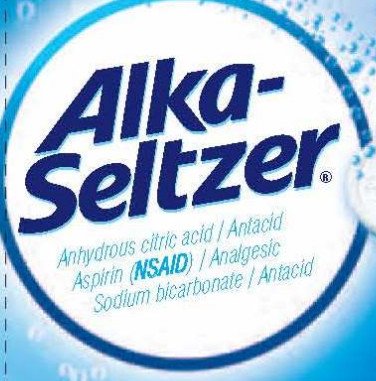


LOT & EXP  
(Bright Background for Black Printing)



**EXTRA STRENGTH**

**Fast Relief of:**  
Heartburn  
Upset Stomach  
Acid Indigestion  
with Headache  
Body Aches



Anhydrous citric acid / Antacid  
Aspirin (NSAID) / Analgesic  
Sodium bicarbonate / Antacid

**Fast Relief of:**  
Heartburn  
Upset Stomach  
Acid Indigestion  
with Headache  
Body Aches

**EXTRA STRENGTH**



24 EFFERVESCENT TABLETS



**EXTRA STRENGTH**



Place two (2) tablets  
in 4 oz. of water.  
Dissolve tablets completely.  
You do not have to drink any  
of the residue that may be on  
the bottom of the glass. The  
medicines of Alka-Seltzer®  
are in the water.



Take Alka-Seltzer® any time –  
morning, noon, or night –  
when you need relief from  
heartburn, upset stomach,  
acid indigestion with headache  
or body aches.

84200913

Dist. by  
Bayer Healthcare LLC  
Whippany, NJ 07981  
Bayer, the Bayer Cross and  
Alka-Seltzer are registered  
trademarks of Bayer.



Pharma Code

GLUE AREA

GLUE AREA

12

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

**Directions**  
● fully dissolve 2 tablets in 4 ounces of water before taking  
● adults and children 12 years and over: 2 tablets every 6 hours, or as directed by a doctor. Do not exceed 7 tablets in 24 hours.  
● children under 12 years: consult a doctor

**Other Information**  
● each tablet contains: sodium 588 mg  
● store at room temperature. Avoid excessive heat and humidity.  
● this product in water contains principally the anhydrous sodium citrate and the analgesic sodium acetylsalicylate

**Inactive Ingredients** Flavor

**Questions or comments?**  
1-800-996-0969 (Mon-Fri 9AM - 5PM EST)

**When using this product do not exceed recommended dosage**

**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
- symptoms get worse or last more than 10 days
- have stomach pain that does not get better
- redness or swelling is present
- ringing in the ears or a loss of hearing occurs
- new symptoms occur

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# ALKA-SELTZER EXTRA STRENGTH

anhydrous citric acid, sodium bicarbonate, and aspirin granule, effervescent

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0280-0211
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	1000 mg
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO) (SODIUM CATION - UNII:L4YR4M0NH37)	SODIUM BICARBONATE	1985 mg
<b>ASPIRIN</b> (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	500 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>LEMON</b> (UNII: 24RS0A988O)	

## Product Characteristics

<b>Color</b>	white (White tablet)	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	25mm
<b>Flavor</b>		<b>Imprint Code</b>	ALKA;SELTZER;EX;S
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0280-0211-24	12 in 1 CARTON	04/18/2011	
1		2 in 1 PACKET; 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	04/11/2011	

**Labeler** - Bayer HealthCare LLC. (112117283)