

ALKA-SELTZER ORIGINAL- anhydrous citric acid, aspirin, and sodium bicarbonate tablet, effervescent

Your Safety Company

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.

Alka-Seltzer® Original

Drug Facts

Active ingredients (in each tablet)	Purpose
Anhydrous citric acid 1000 mg	Antacid
Aspirin 325 mg (NSAID)*	Analgesic
Sodium bicarbonate (heat-treated) 1916 mg	Antacid

* nonsteroidal anti-inflammatory drug

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 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

Directions

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

adults and children 12 years and over	2 tablets every 4 hours, or as directed by a doctor	do not exceed 8 tablets in 24 hours
adults 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 567 mg

- store at room temperature. Avoid excessive heat.
- Alka-Seltzer in water contains principally the antacid sodium citrate and the analgesic sodium acetylsalicylate

Inactive ingredients

none

Questions or comments?

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

Dist. by: Bayer HealthCare LLC

Whippany, NJ 07981

PRINCIPAL DISPLAY PANEL - 50 Pouch Box

***Alka-
Seltzer®***

Anhydrous citric acid / Antacid

Aspirin (NSAID) / Analgesic

Sodium bicarbonate / Antacid

Fast Relief of:

Heartburn

Upset Stomach

Acid Indigestion

with Headache

Body Aches

ORIGINAL

EFFERVESCENT TABLETS

Alka-Seltzer

ORIGINAL

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

Alka-Seltzer

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

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

ORIGINAL

BAYER

EFFERVESCENT TABLETS

Alka-Seltzer

ORIGINAL

Use Only If Pouch Is Sealed
To Open,
PUSH IN TAB and PULL OUT

50 Pouches of 2 Tablets Each

Drug Facts	
Active ingredients (in each tablet).....	Purpose
Anhydrous citric acid 1000 mg.....	Antacid
Aspirin 325 mg (NSAID)*.....	Analgesic
Sodium bicarbonate (heat-treated) 1916 mg.....	Antacid
*nonsteroidal anti-inflammatory drug	
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.	

Alka-Seltzer

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 doctor before using 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. Aspirin may interact with certain prescription drugs. • taking a prescription drug for 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 gets worse or lasts 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 specifically 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	Take 2 tablets every 4 hours or as directed by a doctor, do not exceed 8 tablets in 24 hours
• Adults and children 12 years of age and older.	
• adults 60 years and over	Take 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 567 mg
 • store at room temperature. Avoid excessive heat.
 • Alka-Seltzer in water contains principally the antacid sodium citrate and the analgesic sodium acetylsalicylate

Inactive Ingredients: none

Questions or comments? 1-800-986-0369 (Mon – Fri 9AM – 5PM EST) or www.alkaseltzer.com

ORIGINAL



Directions: Fully dissolve 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.

This Product is repackaged by Your Safety Company, Inc
 Chambersburg PA 17202, 1-800-548-3920 (Mon-Fri 8:00am - 5:00pm EST)
 from a product manufactured by Bayer. Bayer, the Bayer Cross and
 Alka-Seltzer are registered trademarks of Bayer used with permission.
 Bayer HealthCare LLC Whippany, NJ 07891

ALKA-SELTZER ORIGINAL

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70262-304(NDC:0280-4000)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	1000 mg
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 mg
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (BICARBONATE ION - UNII:HN1ZRA3Q20)	SODIUM BICARBONATE	19.16 mg

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	25mm

Flavor		Imprint Code	ALKA;SELTZER	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70262-304-50	50 in 1 BOX		
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 not final	part343	03/15/2016		

Labeler - Your Safety Company (050622331)

Establishment			
Name	Address	ID/FEI	Business Operations
Your Safety Company		050622331	RELABEL(70262-304)

Revised: 3/2016

Your Safety Company