ALKA SELTZER ORIGINAL- anhydrous citric acid, aspirin, sodium bicarbonate tablet, effervescent
Navajo Manufacturing Company 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.

Alka Seltzer Original

Drug Facts

Active ingredients (in each tablet)

Anhydrous citric acid 1000 mg

Aspirin 325 mg (NSAID)*

Sodium bicarbonate (heat-treated) 1916 mg

*nonsteroidal anti-inflammatory drug

Purposes

Antacid

Analgesic

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

fully dissolve 2 tablets in 4 ounces of water before taking

adults and children	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

- do not use if pouch is opened
- 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

Water

Questions or comments?

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

Package Labeling:

ALKA SELTZER ORIGINAL

anhydrous citric acid, aspirin, sodium bicarbonate tablet, effervescent

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67751-143(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) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM BICARBONATE	1916 mg

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

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:67751-143-01	1 in 1 CARTON	09/16/2016	
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:67751-143-02	2 in 1 CARTON	09/16/2016	
2		4 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	09/16/2016	04/01/2025

Labeler - Navajo Manufacturing Company Inc. (091917799)

Establishment

Name	Address	ID/FEI	Business Operations
Navajo Manufacturing Company Inc.		136941411	relabel(67751-143) , repack(67751-143)

Revised: 3/2023