

ALKA-SELTZER ORIGINAL- aspirin, citric acid, sodium bicarbonate tablet SALIMEX, S.A.

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

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

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

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

Active ingredients (in each tablet)

Citric acid
 Aspirin (NSAID)*
 Sodium bicarbonate (heat-treated)
 *nonsteroidal anti-inflammatory drug

Purpose

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

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

Questions or comments?

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

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

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 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
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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

Front and Back



<p>Drug Facts</p> <p>Active ingredients Aspirin (acetylsalicylic acid) 325 mg Sodium bicarbonate 1000 mg Citric acid 100 mg</p> <p>Purpose To relieve minor aches and pains, reduce fever, and relieve heartburn and indigestion.</p> <p>Uses To relieve minor aches and pains, reduce fever, and relieve heartburn and indigestion.</p> <p>Warnings Do not take if you are allergic to aspirin or any of the other ingredients. Do not take if you are taking other aspirin-containing products. Do not take if you are taking other salicylate-containing products. Do not take if you are taking other NSAID-containing products. Do not take if you are taking other blood-thinning drugs. Do not take if you are taking other drugs that may interact with aspirin. Do not take if you are taking other drugs that may interact with sodium bicarbonate. Do not take if you are taking other drugs that may interact with citric acid.</p> <p>Directions Adults and children 12 years of age and older: 1 tablet every 4 hours, as needed, for relief of minor aches and pains, fever, or heartburn and indigestion. Do not exceed 12 tablets in 24 hours. Do not take for more than 3 days for fever or pain, or more than 7 days for heartburn and indigestion. Do not take for more than 10 days for heartburn and indigestion. Do not take for more than 10 days for heartburn and indigestion.</p> <p>Other information Contains 12 tablets. Each tablet contains 325 mg of aspirin, 1000 mg of sodium bicarbonate, and 100 mg of citric acid. Contains 12 tablets. Each tablet contains 325 mg of aspirin, 1000 mg of sodium bicarbonate, and 100 mg of citric acid.</p> <p>Contains 12 tablets. Each tablet contains 325 mg of aspirin, 1000 mg of sodium bicarbonate, and 100 mg of citric acid.</p>	<p>Drug Facts (continued)</p> <p>Directions (continued) Children 6 to 11 years of age: 1 tablet every 4 hours, as needed, for relief of minor aches and pains, fever, or heartburn and indigestion. Do not exceed 6 tablets in 24 hours. Do not take for more than 3 days for fever or pain, or more than 7 days for heartburn and indigestion. Do not take for more than 10 days for heartburn and indigestion.</p> <p>Other information (continued) Contains 12 tablets. Each tablet contains 325 mg of aspirin, 1000 mg of sodium bicarbonate, and 100 mg of citric acid. Contains 12 tablets. Each tablet contains 325 mg of aspirin, 1000 mg of sodium bicarbonate, and 100 mg of citric acid.</p> <p>Contains 12 tablets. Each tablet contains 325 mg of aspirin, 1000 mg of sodium bicarbonate, and 100 mg of citric acid.</p>	<p>Drug Facts (continued)</p> <p>Directions (continued) Do not take if you are pregnant, planning to get pregnant, or are breastfeeding. Do not take if you are taking other aspirin-containing products. Do not take if you are taking other salicylate-containing products. Do not take if you are taking other NSAID-containing products. Do not take if you are taking other blood-thinning drugs. Do not take if you are taking other drugs that may interact with aspirin. Do not take if you are taking other drugs that may interact with sodium bicarbonate. Do not take if you are taking other drugs that may interact with citric acid.</p> <p>Other information (continued) Contains 12 tablets. Each tablet contains 325 mg of aspirin, 1000 mg of sodium bicarbonate, and 100 mg of citric acid. Contains 12 tablets. Each tablet contains 325 mg of aspirin, 1000 mg of sodium bicarbonate, and 100 mg of citric acid.</p> <p>Contains 12 tablets. Each tablet contains 325 mg of aspirin, 1000 mg of sodium bicarbonate, and 100 mg of citric acid.</p>
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ALKA-SELTZER ORIGINAL

aspirin, citric acid, sodium bicarbonate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53666-218
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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Ingredient Name	Basis of Strength	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	1000 mg
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (BICARBONATE ION - UNII:HN1ZRA3Q20)	SODIUM BICARBONATE	1916 mg
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 mg

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	14mm
Flavor		Imprint Code	ALKA;SELTZER
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53666-218-14	150 in 1 BOX	10/03/2017	
1	NDC:53666-218-13	6 in 1 BOX		
1	NDC:53666-218-12	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	10/03/2017	

Labeler - SALIMEX, S.A. (589201581)

Registrant - SALIMEX, S.A. (589201581)

Establishment

Name	Address	ID/FEI	Business Operations
Bayer de México, S.A. de C.V.		588165709	manufacture(53666-218)

Establishment

Name	Address	ID/FEI	Business Operations
Salimex, S.A.		589201581	relabel(53666-218)

