

ALKA-SELTZER ORIGINAL- aspirin, citric acid, sodium bicarbonate tablet
Impulsora Sahuayo, S.A. de C.V

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</p> <p>Aspirin (acetylsalicylic acid) 325 mg</p> <p>Sodium bicarbonate 1000 mg</p> <p>Citric acid 1000 mg</p>	<p>Drug Facts (continued)</p> <p>Aspirin (acetylsalicylic acid) is a nonsteroidal anti-inflammatory drug (NSAID) that relieves pain, reduces inflammation, and lowers fever. It also helps to reduce the risk of heart disease and stroke.</p> <p>Do not use if:</p> <ul style="list-style-type: none"> you are allergic to aspirin or any other pain reliever from salicylic acid you have ever had an allergic reaction to this product or any of its ingredients <p>Use cautiously:</p> <ul style="list-style-type: none"> if you are taking blood thinners if you have a history of stomach ulcers or bleeding if you have a history of kidney disease if you have a history of liver disease if you have a history of asthma if you have a history of heart disease if you have a history of high blood pressure if you have a history of diabetes if you have a history of gout if you have a history of peptic ulcers if you have a history of bleeding disorders if you have a history of alcoholism if you have a history of liver or kidney disease if you have a history of heart failure if you have a history of low blood sodium if you have a history of low blood potassium if you have a history of low blood calcium if you have a history of low blood magnesium if you have a history of low blood zinc if you have a history of low blood iron if you have a history of low blood copper if you have a history of low blood manganese if you have a history of low blood selenium if you have a history of low blood iodine if you have a history of low blood cobalt if you have a history of low blood molybdenum if you have a history of low blood vanadium if you have a history of low blood chromium if you have a history of low blood nickel if you have a history of low blood boron if you have a history of low blood silicon if you have a history of low blood phosphorus if you have a history of low blood sulfur if you have a history of low blood chlorine if you have a history of low blood bromine if you have a history of low blood strontium if you have a history of low blood barium if you have a history of low blood calcium if you have a history of low blood magnesium if you have a history of low blood potassium if you have a history of low blood sodium if you have a history of low blood zinc if you have a history of low blood iron if you have a history of low blood copper if you have a history of low blood manganese if you have a history of low blood selenium if you have a history of low blood iodine if you have a history of low blood cobalt if you have a history of low blood molybdenum if you have a history of low blood vanadium if you have a history of low blood chromium if you have a history of low blood nickel if you have a history of low blood boron if you have a history of low blood silicon if you have a history of low blood phosphorus if you have a history of low blood sulfur if you have a history of low blood chlorine if you have a history of low blood bromine if you have a history of low blood strontium if you have a history of low blood barium 	<p>Drug Facts (continued)</p> <p>Directions</p> <p>Take 1 tablet 2-3 times a day with meals or after meals.</p> <p>Other information</p> <p>Keep out of reach of children. If used for more than 10 days, stop and ask your doctor.</p> <p>Warnings</p> <p>Do not use if you are allergic to aspirin or any other pain reliever from salicylic acid.</p> <p>Do not use if you have ever had an allergic reaction to this product or any of its ingredients.</p> <p>Do not use if you have a history of stomach ulcers or bleeding.</p> <p>Do not use if you have a history of kidney disease.</p> <p>Do not use if you have a history of liver disease.</p> <p>Do not use if you have a history of asthma.</p> <p>Do not use if you have a history of heart disease.</p> <p>Do not use if you have a history of high blood pressure.</p> <p>Do not use if you have a history of diabetes.</p> <p>Do not use if you have a history of gout.</p> <p>Do not use if you have a history of peptic ulcers.</p> <p>Do not use if you have a history of bleeding disorders.</p> <p>Do not use if you have a history of alcoholism.</p> <p>Do not use if you have a history of liver or kidney disease.</p> <p>Do not use if you have a history of heart failure.</p> <p>Do not use if you have a history of low blood sodium.</p> <p>Do not use if you have a history of low blood potassium.</p> <p>Do not use if you have a history of low blood calcium.</p> <p>Do not use if you have a history of low blood magnesium.</p> <p>Do not use if you have a history of low blood zinc.</p> <p>Do not use if you have a history of low blood iron.</p> <p>Do not use if you have a history of low blood copper.</p> <p>Do not use if you have a history of low blood manganese.</p> <p>Do not use if you have a history of low blood selenium.</p> <p>Do not use if you have a history of low blood iodine.</p> <p>Do not use if you have a history of low blood cobalt.</p> <p>Do not use if you have a history of low blood molybdenum.</p> <p>Do not use if you have a history of low blood vanadium.</p> <p>Do not use if you have a history of low blood chromium.</p> <p>Do not use if you have a history of low blood nickel.</p> <p>Do not use if you have a history of low blood boron.</p> <p>Do not use if you have a history of low blood silicon.</p> <p>Do not use if you have a history of low blood phosphorus.</p> <p>Do not use if you have a history of low blood sulfur.</p> <p>Do not use if you have a history of low blood chlorine.</p> <p>Do not use if you have a history of low blood bromine.</p> <p>Do not use if you have a history of low blood strontium.</p> <p>Do not use if you have a history of low blood barium.</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:69670-218
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
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:69670-218-14	150 in 1 BOX	07/28/2021	
1	NDC:69670-218-13	6 in 1 BOX		
1	NDC:69670-218-12	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	07/28/2021	

Labeler - Impulsora Sahuayo, S.A. de C.V (812782885)

Registrant - Impulsora Sahuayo, S.A. de C.V (812782885)

Establishment

Name	Address	ID/FEI	Business Operations
Bayer de México, S.A. de C.V.		588165709	manufacture(69670-218)

Establishment

Name	Address	ID/FEI	Business Operations
Impulsora Sahuayo, S.A. de C.V		812782885	relabel(69670-218)

