

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

***Active Ingredients
(in each tablet)***

Aspirin 325 mg

Citric acid 1000 mg

Sodium Bicarbonate (heat treated) 1916 mg

Purpose

Analgesic, Antacid

Keep out of reach of children

In case of overdose, get medical help or contact a Poison Control Center right away.

Uses for the 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 should not use this medicine for chicken pox or flu symptoms before a doctor is consulted about Reye's syndrome, a rare but serious illness reported to be associated with aspirin.

Allergy alert: Aspirin may cause a severe allergic reaction which may include:

- hives
- asthma (wheezing)

Alcohol warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take aspirin or other pain relievers/fever reducers. Aspirin may cause stomach bleeding.

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)
or www.alkaseltzer.com



ALKA SELTZER			
aspirin, anhydrous citric acid, sodium bicarbonate tablet, effervescent			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53666-403
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 mg
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	1000 mg
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (BICARBONATE ION - UNII:HN1ZRA3Q20)	BICARBONATE ION	19 16 mg

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:53666-403-15	150 in 1 CASE		
1	NDC:53666-403-33	12 in 1 BOX		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	10/10/2012	

ALKA SELTZER

aspirin, anhydrous citric acid, sodium bicarbonate tablet, effervescent

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53666-100
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 mg
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	1000 mg
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (BICARBONATE ION - UNII:HN1ZRA3Q20)	BICARBONATE ION	19 16 mg

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:53666-100-10	100 in 1 BOX		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	10/10/2012	

Labeler - Salimex, S.A. (589201581)**Establishment**

Name	Address	ID/FEI	Business Operations
Bayer de Mexico, S.A. de CV		588165709	manufacture(53666-403)

Revised: 11/2012

Salimex, S.A.