# ALKA-SELTZER HEARTBURN RELIEF EXTRA STRENGTH- anhydrous citric acid, sodium bicarbonate (heat-treated) tablet, effervescent Bayer Healthcare LLC

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 Heartburn Relief Extra Strength

#### **Drug Facts**

Anhydrous citric acid 1000 mg

Sodium bicarbonate (heat-treated) 1976 mg

**Antacid** 

**Antacid** 

**Uses** for the relief of

- heartburn
- acid indigestion
- sour stomach
- upset stomach associated with these symptoms

#### Warnings

**Do not use** if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if 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.

When using this product do not exceed recommended dosage

Stop use and ask a doctor if you have taken the maximum dose for 2 weeks

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

#### **Directions**

fully dissolve 2 tablets in 4 ounces of water before taking

adults and children 12	2 tablets every 4 hours as needed, or	do not exceed 8
years and over	as directed by a doctor	tablets in 24 hours
adults 60 years and	2 tablets every 4 hours as needed, or	do not exceed 4
over	as directed by a doctor	tablets in 24 hours
children under 12 years	consult a doctor	

- each tablet contains: sodium 586 mg
- store at room temperature. Avoid excessive heat.
- Alka-Seltzer Extra Strength in water contains the antacid sodium citrate as the principal active ingredient

#### Inactive ingredients

magnesium stearate, mannitol

**Questions or comments? 1-800-986-0369** (Mon – Fri 9AM – 5PM EST)

**ALKA-SELTZER** 

Fast 4-in-1

Relief of:

Heartburn

Sour Stomach

**Acid Indigestion** 

**Upset Stomach** 

**HEARTBURN RELIEF** 

**EXTRA STRENGTH** 

24 EFFERVESCENT TABLETS

(12 - 2 count pouches)



### **ALKA-SELTZER HEARTBURN RELIEF EXTRA STRENGTH**

anhydrous citric acid, sodium bicarbonate (heat-treated) tablet, effervescent

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0280-0079
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM BICARBONATE	1976 mg		
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	1000 mg		

Inactive Ingredients			
Ingredient Name Strength			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
MANNITOL (UNII: 30WL53L36A)			

Product Characteristics				
Color	white	Score	score with uneven pieces	
Shape	ROUND	Size	25mm	
Flavor		Imprint Code	ALKA;SELTZER;EX;S	
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:0280-0079- 01	12 in 1 CARTON	09/21/2021		
1		2 in 1 PACKET; Type 0: Not a Combination Product			
2	NDC:0280-0079- 02	36 in 1 CARTON	05/23/2023		
2		2 in 1 PACKET; Type 0: Not a Combination Product			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part331	09/21/2021	

## Labeler - Bayer Healthcare LLC (112117283)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
Bayer de Mexico, S.A. de C.V.		588165709	manufacture(0280-0079)

Revised: 5/2023 Bayer Healthcare LLC