ALKA-SELTZER ORIGINAL FLAVOR- alka-seltzer original flavor 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 Original Flavor

Active ingredient (in each tablet)

Buffered aspirin 325 mg (NSAID)*

Pain reliever/fever reducer

*nonsteroidal anti-inflammatory drug

Uses

● temporarily relieves minor aches and pains due to:

● headache ● muscle pain ● backache

● toothache ● menstrual pain ● colds

● minor pain of arthritis

● temporarily reduces fever

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 taking a prescription drug for

● diabetes ● gout ● arthritis

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

● pain gets worse or last more than 10 days

● fever gets worse or last more than 3 days

● redness or swelling is present

● new symptoms occur

● ringing in the ears or a loss of hearing occurs

If pregnant or breast-feeding, ask a health professional before use. **It is especially important not to use aspirin at 20 weeks or later in 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 12	2 tablets every 4 hours, or as	do not exceed 8 tablets

years and over	directed by a doctor	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 568 mg

● store at room temperature. Avoid excessive heat.

● Alka-Seltzer Original Flavor in water contains principally the analgesic sodium acetylsalicylate

Inactive Ingredients anhydrous citric acid, sodium bicarbonate

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

Alka-Seltzer

Buffered Aspirin (NSAID) / Pain reliever / fever reducer

Fast Relief of:
Headache
Backache
Body Aches
Muscle Pain

ORIGINAL FLAVOR

24 EFFERVESCENT TABLETS

(12 - 2 count pouches)

ALKA-SELTZER ORIGINAL FLAVOR

alka-seltzer original flavor tablet, effervescent

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0280-0087
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 mg

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	1000 mg
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	1916 mg

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:0280-0087-04	12 in 1 CARTON	03/03/2022	
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:0280-0087-02	18 in 1 CARTON	03/03/2022	
2		2 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:0280-0087-03	36 in 1 CARTON	04/04/2022	
3		2 in 1 POUCH; Type 0: Not a Combination Product		
4	NDC:0280-0087-01	6 in 1 CARTON	04/18/2023	
4		2 in 1 POUCH; Type 0: Not a Combination Product		
5	NDC:0280-0087-06	58 in 1 CARTON	04/26/2023	
5		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	03/03/2022	

Labeler - Bayer HealthCare LLC. (112117283)

Revised: 4/2023 Bayer HealthCare LLC.