

ALKA-SELTZER HANGOVER RELIEF- anhydrous citric acid, aspirin, and sodium bicarbonate 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 Hangover Relief

Drug Facts

Active Ingredients (in each tablet)

Aspirin 500 mg (NSAID)*

Caffeine 65 mg

*nonsteroidal anti-inflammatory drug

Pain reliever

Alertness aid/pain reliever aid

Uses

Uses

- for the temporary relief of minor aches and pains associated with a hangover
- helps restore mental alertness or wakefulness when experiencing fatigue or drowsiness associated with a hangover
- for temporary relief of headaches, body aches, and pain alone

Warnings

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

Caffeine warning: The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine- containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heart beat.

● For occasional use only. Do not use for more than 2 days for a hangover unless directed by a doctor. Not intended for use as a substitute for sleep. If fatigue or drowsiness persists or continues to recur, consult a doctor.

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

Caffeine warning

The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine- containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heart beat.

● For occasional use only. Do not use for more than 2 days for a hangover unless directed by a doctor. Not intended for use as a substitute for sleep. If fatigue or drowsiness persists or continues to recur, consult a doctor.

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 lasts for more than 10 days or gets worse
- redness or swelling is present
- ringing in the ears or a loss of hearing occurs
- new symptoms occur

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***Directions***

- fully dissolve 2 tablets in 4 ounces of water before taking

Adults 18 years and over	2 tablets every 6 hours as needed, or as directed by a doctor	do not exceed 8 tablets in 24 hours
Adults 60 years and over	2 tablets every 6 hours as needed, or as directed by a doctor	do not exceed 5 tablets in 24 hours
Children under 18		

Children under 10 years consult a doctor

Other information

- each tablet contains: potassium 115 mg
- each tablet contains: sodium 371 mg
- **Phenylketonurics:** Contains Phenylalanine 5.4 mg per tablet
- store at room temperature. Avoid excessive heat

Inactive ingredients

anhydrous citric acid, aspartame, dimethicone, docusate sodium, FD&C red No. 40, FD&C yellow No. 6, flavor, mannitol, potassium bicarbonate, povidone, sodium benzoate, sodium bicarbonate, sucralose

Questions or comments?

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

Dist. by: Bayer HealthCare LLC

Whippany, NJ 07981

PRINCIPAL DISPLAY PANEL - 20 Tablet Carton



Alka-Seltzer®

HANGOVER RELIEF

orange fizz

FAST RELIEF OF
headache, body aches
mental fatigue

20EFFERVESCENT TABLETS
10 - 2 count pouches

ALKA-SELTZER HANGOVER RELIEF

anhydrous citric acid, aspirin, and sodium bicarbonate tablet, effervescent

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0280-0084
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	500 mg

Inactive Ingredients

Ingredient Name	Strength
ASPARTAME (UNII: Z0H242BBR1)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
DOCUSATE SODIUM (UNII: F05Q2T2JA0)	
DIMETHICONE 100 (UNII: RO266O364U)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	25mm
Flavor		Imprint Code	A;S
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0280-0084-01	10 in 1 CARTON	02/21/2022	
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:0280-0084-02	18 in 1 CARTON	04/19/2023	
2		2 in 1 POUCH; Type 0: Not a Combination Product		
	NDC:0280-0084			

3	NDC:0280-0084-03	60 in 1 CARTON	04/19/2023	
3		2 in 1 POUCH; Type 0: Not a Combination Product		
4	NDC:0280-0084-04	2 in 1 CARTON	04/19/2023	
4		2 in 1 POUCH; Type 0: Not a Combination Product		
5	NDC:0280-0084-05	1600 in 1 BOX	05/23/2023	
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 final	M013	02/21/2022	

Labeler - Bayer HealthCare LLC. (112117283)

Revised: 5/2023

Bayer HealthCare LLC.