FAMILY WELLNESS EFFERVESCENT ANTACID AND PAIN RELIEF- aspirin, citric acid, sodium bicarbonate tablet, effervescent Family Wellness Services, Inc.

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.

Family Wellness Effervescent Antacid & Pain Relief

Purpose

Active ingredients

Aspirin 325 mg (NSAID)*

Citric acid 1000 mg

Sodium bicarbonate (heat-treated) 1916 mg

Uses for the temporary relief of

- heartburn, acid indigestion and sour stomach when accompanied by headache or body aches and pains
- upset stomach with headache from overindulgence in food or drink
- pain alone (headaches or body aches and pains)

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 a nonsteroidal anti-inflammatory drug (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 have ever had an allergic reaction to any other pain reliever/fever reducer
- if you are allergic to aspirin if overly full from food or drink. Ask a doctor if severe stomach pain

^{*}Nonsteroidal anti-inflammatory drug

occurs after taking this product.

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 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.
- taking a prescription drug for anticoagulation (thinning the blood), diabetes, gout or arthritis

When using this product

do not take more than 8 tablets (adults) or 4 tablets (60 years and over) in a 24-hour period or use the maximum dosage for more than 10 days

Stop use and ask a doctor if

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
- an allergic reaction occurs. Seek medical help right away.
- pain lasts for more than 10 days or gets worse
- new symptoms occur
- redness or swelling is present
- 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 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.

In case of overdose

get medical help or contact a Poison Control Center right away.

Directions

- do not exceed recommended dosage
- to avoid serious injury, completely dissolve tablets in 4 oz. of water before taking
- adults and children 12 years and over (up to 60 years of age): 2 tablets every 4 hours do not exceed 8 tablets in 24 hours

■ 60 years and over: 2 tablets every 4 hours - do not exceed 4 tablets in 24 hours

Other information

■ each tablet contains: sodium 524 mg

■ store at room temperature (59°-86°F)

Inactive ingredients

■ none

Serious side effects associated with the use of this product can be reported to the following address:

 $Distributed\ by: Midwood\ Brands,\ LLC$

10611 Monroe Rd, Matthews, NC 28105

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



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Drug Facts (continued)

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(in each tablet) Purpose Active ingredients

Drug Facts

COMPARE TO ALKA-SELTZER®*

wellness*

EFFERVESCENT

Antacid & Pain Relief

For Relief of: Acid Indigestion • Heartburn with Headache

 Body Aches 24 TABLETS



ORIGINAL FLAVOR



COMPARE TO ALKA-SELTZER™





Drug Facts (continued)

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EFFERVESCENT

Antacid & Pain Relief

Aspirin (NSAID)/Pain Reliever Citric Acid/Antacid Sodium Bicarbonate/Antacid

For Relief of: Acid Indigestion

• Heartburn with Headache

• Body Aches



ORIGINAL FLAVOR



24 TABLETS

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DISTRIBUTED BY: MIDWOOD BRANDS, LLC 10611 MONROE RD., MATTHEWS, NC 28105

NOT 100% SATISFIED? Return package and unused product within 30 days to any Family Dollar store for a refund (with receipt) or exchange.

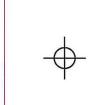
*This product is not manufactured or distributed by Bayer Corporation owner of the registered trademark Alka-Seltzer® .

Manufactured in the USA with domestic and imported ingredients



DO NOT USE IF PRINTED PACKETS ARE TORN OR PUNCTURED

PN: 42124 FA C1 R: 11/17





FAMILY WELLNESS EFFERVESCENT ANTACID AND PAIN RELIEF

aspirin, citric acid, sodium bicarbonate tablet, effervescent

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55319-421
Route of Administration	ORAL		

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

Product Characteristics				
Color	white	Score	no score	
Shape	ROUND	Size	25mm	
Flavor		Imprint Code	L421	
Contains				

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55319-421-36	36 in 1 CARTON	06/13/2017	
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:55319-421-24	24 in 1 CARTON	12/16/2017	
2		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	part343	06/13/2017	

Labeler - Family Wellness Services, Inc. (024472631)

Revised: 5/2019 Family Wellness Services, Inc.