

**EFFERVESCENT PAIN RELIEF- aspirin, citric acid monohydrate, and sodium bicarbonate tablet, effervescent**  
**Western Family Foods, 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.*

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**Effervescent Pain Relief**

**Drug Facts**

<b>Active ingredients (in each effervescent tablet)</b>	<b>Purpose</b>
Aspirin (NSAID)* 325 mg	Pain reliever
Citric acid 1000 mg	Antacid
Sodium bicarbonate (heat-treated) 1916 mg	Antacid

\* nonsteroidal anti-inflammatory drug

**Uses**

**For the temporary 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
- 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 NSAID's (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for longer time than directed

**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.

**Do not use if**

- you have ever had an allergic reaction to any other pain reliever/fever reducer
- you are allergic to aspirin

**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

**Ask a doctor or pharmacist before use if**

- 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 exceed the recommended dosage****Stop use and ask a doctor if**

- an allergic reaction occurs. Seek medical help right away
- you have 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
- 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**

- completely dissolve tablets in 4 ounces of water before taking

Adults and children 12 years and over	2 tablets every 4 hours do not exceed 8 tablets in 24 hours
60 years and older	2 tablets every 4 hours do not exceed 4 tablets in 24 hours

**Other Information**

- **each tablet contains:** sodium 540 mg
- protect from excessive heat
- in water, this tablet contains principally the antacid sodium citrate and the analgesic sodium acetylsalicylate

**Inactive Ingredients**

none

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**PRINCIPAL DISPLAY PANEL - 36 Tablet Carton**

**WESTERN  
FAMILY®**

Antacid & Pain Relief Medicine

*Effervescent*

**PAIN RELIEF**

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

***FAST RELIEF OF:***

*Acid Indigestion, Upset Stomach, Heartburn  
With Headache, Body Aches & Pains*

**36  
TABLETS**

*COMPARE TO ALKA-SELTZER®* active ingredients\*



**36**  
TABLETS

Antacid & Pain Relief Medicine  
**Effervescent**  
**PAIN RELIEF**



Antacid & Pain Relief Medicine.  
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**PAIN RELIEF**

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Antacid, Sodium Bicarbonate / Antacid**

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**36**  
TABLETS

COMPARE TO ALKA-SELTZER® active ingredients\*



Antacid & Pain Relief Medicine  
**Effervescent**  
**PAIN RELIEF**

Take this product any time - morning, noon or night -  
when you need relief from heartburn, acid indigestion,  
sour stomach with headache or body aches and pains.

**DIRECTIONS:** Place two (2) tablets in 4 oz. of water.  
Dissolve tablets completely. You do not have to drink  
any of the residue that may be on the bottom of the  
glass. The medicines are in the water.

**TABLETS SEALED IN PRINTED PACKETS  
FOR YOUR PROTECTION**

**DO NOT USE IF PRINTED PACKETS  
ARE TORN OR PUNCTURED**

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BOXD-143 REV-0

03137-D-DESE



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## Drug Facts

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Citric acid 1000 mg.....	Antacid
Sodium bicarbonate (heat-treated) 1916 mg.....	Antacid

### Uses

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### 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 ■ facial swelling ■ asthma (wheezing) ■ shock

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- 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 NSAID's (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
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**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.

**Do not use if:** ■ you have ever had an allergic reaction to any other pain reliever/fever reducer ■ you are allergic to aspirin

**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

**Ask a doctor or pharmacist before use if:**

- 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 exceed the recommended dosage** ▶

## Drug Facts (continued)

**Stop use and ask a doctor if:**

- an allergic reaction occurs. Seek medical help right away
- you have 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
- new symptoms occur
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### Other Information

- each tablet contains: sodium 540mg
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**Inactive Ingredients** none

\*Alka-Seltzer® is a registered trademark of Bayer HealthCare LLC, Morristown, NJ 07962. This product is not distributed by Bayer HealthCare LLC.

## EFFERVESCENT PAIN RELIEF

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

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55312-469
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Aspirin (UNII: R16CO5Y76E) (Aspirin - UNII:R16CO5Y76E)	Aspirin	325 mg
Citric Acid Monohydrate (UNII: 2968PHW8QP) (Anhydrous Citric Acid - UNII:XF417D3PSL)	Anhydrous Citric Acid	1000 mg
Sodium Bicarbonate (UNII: 8MDF5V39QO) (Bicarbonate Ion - UNII:HN1ZRA3Q20)	Sodium Bicarbonate	1916 mg

### Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	2 pieces
<b>Shape</b>	ROUND	<b>Size</b>	25mm
<b>Flavor</b>		<b>Imprint Code</b>	C11
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55312-469-80	18 in 1 CARTON		
1		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	part343	01/28/2008	

**Labeler** - Western Family Foods, Inc. (192166072)