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

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

* 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

<table>
<thead>
<tr>
<th>Adults and children 12 years and over</th>
<th>2 tablets every 4 hours do not exceed 8 tablets in 24 hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>60 years and older</td>
<td>2 tablets every 4 hours do not exceed 4 tablets in 24 hours</td>
</tr>
</tbody>
</table>

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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P.O. Box 4057, Portland, OR 97208 U.S.A.

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

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TABLETS

COMPARE TO ALKA-SELTZER® active ingredients*
**EFFERVESCENT PAIN RELIEF**
aspirin, citric acid monohydrate, and sodium bicarbonate tablet, effervescent

### Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Human OTC Drug</th>
<th>Item Code (Source)</th>
<th>NDC:55312-469</th>
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<tbody>
<tr>
<td>Route of Administration</td>
<td>ORAL</td>
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### Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Aspirin</strong> (UNII: R16CO5Y76E) (Aspirin - UNII:R16CO5Y76E)</td>
<td>Aspirin</td>
<td>325 mg</td>
</tr>
<tr>
<td><strong>Citric Acid Monohydrate</strong> (UNII: 2968PHW8QP) (Anhydrous Citric Acid - UNII:XF417D3PSL)</td>
<td>Anhydrous Citric Acid</td>
<td>1000 mg</td>
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<tr>
<td><strong>Sodium Bicarbonate</strong> (UNII: 8MDF5V39QO) (Bicarbonate Ion - UNII:HNI1ZRA3Q20)</td>
<td>Sodium Bicarbonate</td>
<td>1916 mg</td>
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### Product Characteristics

<table>
<thead>
<tr>
<th>Color</th>
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<th>Score</th>
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<tbody>
<tr>
<td>Shape</td>
<td>ROUND</td>
<td>Size</td>
<td>25mm</td>
</tr>
<tr>
<td>Flavor</td>
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<td>Imprint Code</td>
<td>C11</td>
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<tr>
<td>Contains</td>
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### Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<tbody>
<tr>
<td>1</td>
<td>NDC:55312-469-80</td>
<td>18 in 1 CARTON</td>
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<td></td>
</tr>
<tr>
<td>1</td>
<td></td>
<td>2 in 1 PACKET; Type 0: Not a Combination Product</td>
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### Marketing Information

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<tr>
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<th>Application Number or Monograph Citation</th>
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<td>OTC MONOGRAPH FINAL</td>
<td>part343</td>
<td>01/28/2008</td>
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**Labeler** - Western Family Foods, Inc. (192166072)

Revised: 10/2014