

**TOPCARE EFFERVESCENT ANTACID AND PAIN RELIEF- aspirin, citric acid, sodium bicarbonate tablet, effervescent**  
**Topco Associates 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.*

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**Top Care Effervescent Antacid & Pain Relief**

**Active ingredients**

**(in each effervescent tablet)**

Anhydrous citric acid 1000 mg

Aspirin 325 mg **(NSAID)\***

Sodium bicarbonate (heat-treated) 1916 mg

\*Nonsteroidal anti-inflammatory drug

**Purpose**

Anhydrous citric acid 1000 mg.....Antacid

Aspirin 325 mg **(NSAID)\***.....Pain reliever

Sodium bicarbonate (heat-treated) 1916 mg.....Antacid

\*Nonsteroidal anti-inflammatory drug

**Uses**

**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

■ headache, body aches, and pain alone

**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**

**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**

**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**

**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 2 weeks, except under the advise and supervision of a physician.

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

**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 breastfeeding**

**If pregnant or breastfeeding**, 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.**

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## **In case of overdose**

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 4oz. 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
- Children under 12 years: consult a doctor

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.

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.

## **Other information**

- **each tablet contains:** sodium 524 mg
- store at room temperature (59°-86°F)

## **Inactive ingredients**

- none

## **Questions or comments?**

**1-888-423-0139**

**PACKAGE LABEL. PRINCIPAL DISPLAY PANEL**



## TOPCARE EFFERVESCENT ANTACID AND PAIN RELIEF

aspirin, citric acid, sodium bicarbonate tablet, effervescent

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-421
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ASPIRIN</b> (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 mg
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO) (BICARBONATE ION - UNII:HN1Z RA3Q20)	SODIUM BICARBONATE	1916 mg
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL) (ANHYDROUS CITRIC ACID -	ANHYDROUS CITRIC	1000 mg

UNII:XF417D3PSL)		ACID	1000 mg	
<b>Product Characteristics</b>				
<b>Color</b>	white	<b>Score</b>	no score	
<b>Shape</b>	ROUND	<b>Size</b>	25mm	
<b>Flavor</b>		<b>Imprint Code</b>	L421	
<b>Contains</b>				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:36800-421-68	18 in 1 CARTON	08/11/2014	
1		2 in 1 POUCH; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>		<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part343		08/11/2014	

**Labeler** - Topco Associates LLC (006935977)

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Topco Associates LLC