

**TOP VALUE EFFERVESCENT PAIN RELIEF- aspirin, citric acid, sodium bicarbonate tablet, effervescent**  
**Tower Laboratories Ltd**

*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 Tablets 36 ct.**

**Active Ingredients**

(in each effervescent tablet)

Aspirin 325 mg (NSAID)\*

Citric acid 1000 mg

Sodium bicarbonate (heat-treated) 1916 mg

\*Nonsteroidal anti-inflammatory drug

**Purpose**

Pain reliever

Antacid

Antacid

**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 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:**

Tower Laboratories LTD  
P.O. Box 306  
8 Industrial Park Road  
Centerbrook, CT 06409

**PACKAGE LABEL. PRINCIPAL DISPLAY PANEL**



# TOP VALUE EFFERVESCENT PAIN RELIEF

aspirin, citric acid, sodium bicarbonate tablet, effervescent

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50201-4213
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

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

## Product Characteristics

<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>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50201-4213-6	18 in 1 CARTON	12/01/2006	
1		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	12/01/2006	

**Labeler** - Tower Laboratories Ltd (001587203)

**Registrant** - Tower Laboratories Ltd (869024500)