

**BROMO SELTZER- aspirin, sodium bicarbonate, citric acid 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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**Bromo Seltzer**

**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**

**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**

■ 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) and 4 tablets (60 years and over) in a 24-hour period or use the maximum dosage for more than 2 weeks, except under the advice 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 loss of hearing occurs

### **If pregnant or breast-feeding**

**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
- Children under 12 years: consult a doctor

### **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:

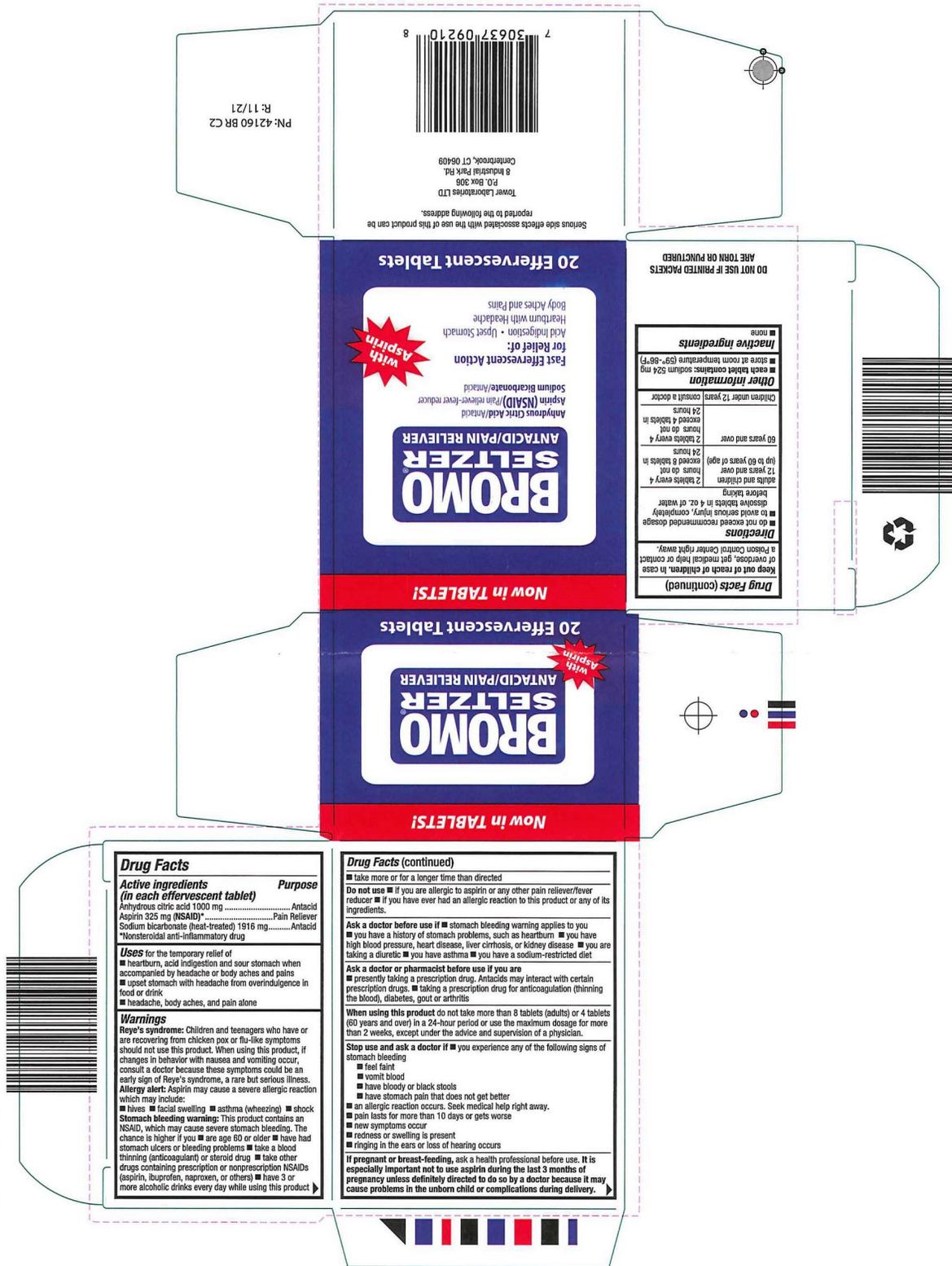
Tower Laboratories LTD.

P.O. Box 306

8 Industrial Park Rd.

Centerbrook, CT 06409

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**



# BROMO SELTZER

aspirin, sodium bicarbonate, citric acid tablet, effervescent

## Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:50201-0421

<b>Route of Administration</b>	ORAL
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### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO) (BICARBONATE ION - UNII:HN1ZRA3Q20)	SODIUM BICARBONATE	1916 mg
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	1000 mg
<b>ASPIRIN</b> (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 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:50201-0421-2	10 in 1 CARTON	07/16/2012	
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	07/16/2012	

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

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

### Establishment

Name	Address	ID/FEI	Business Operations
Tower Laboratories Ltd		869024500	manufacture(50201-0421) , pack(50201-0421) , label(50201-0421)

Revised: 12/2022

Tower Laboratories Ltd