

BROMO SELTZER- aspirin, sodium bicarbonate, citric acid tablet, effervescent

Tower Laboratories Ltd

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 mgAntacid

*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:

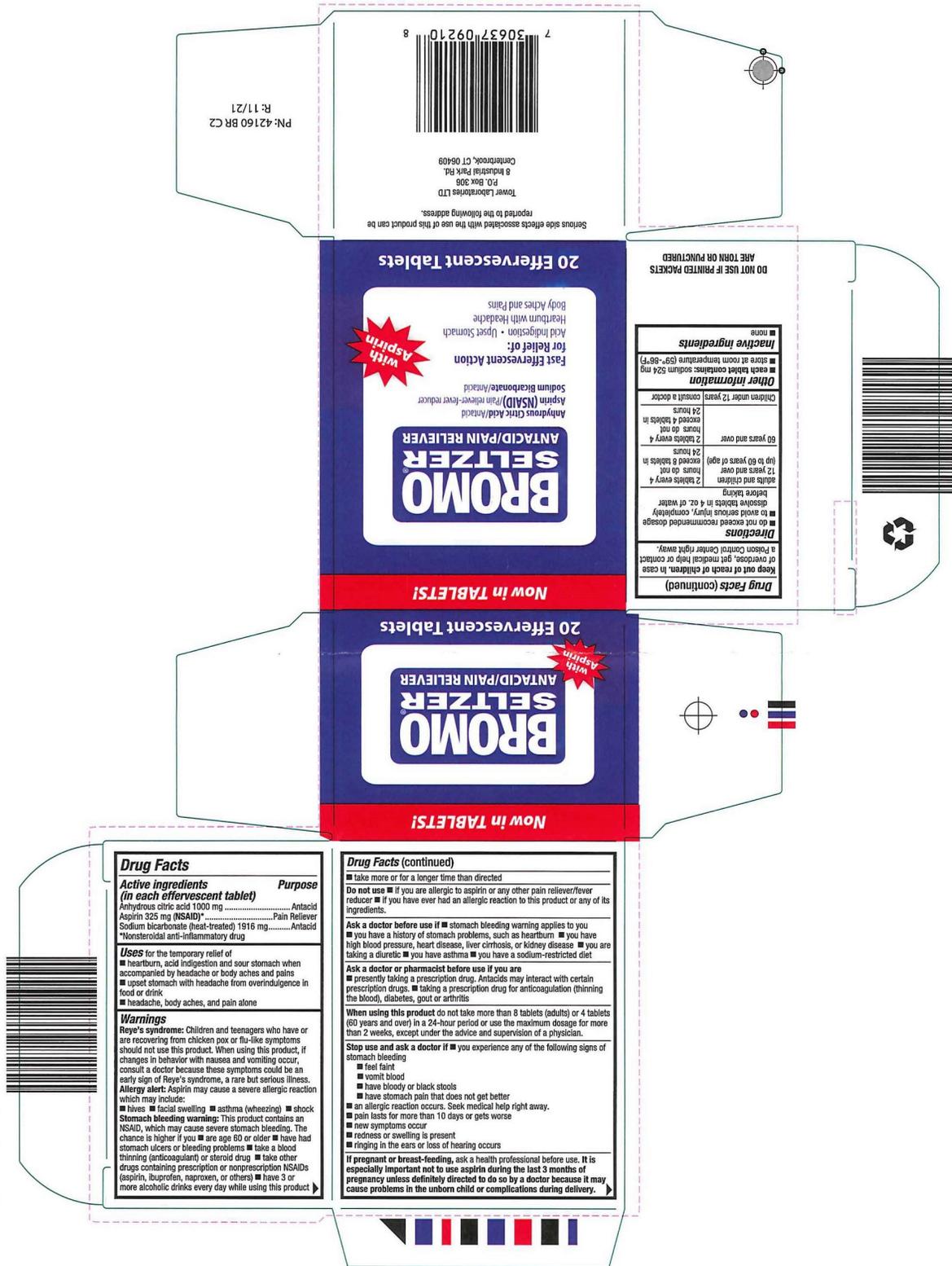
Tower Laboratories LTD.

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

Route of Administration	ORAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (BICARBONATE ION - UNII:HN1ZRA3Q20)	SODIUM BICARBONATE	1916 mg
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	1000 mg
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 mg

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	25mm
Flavor		Imprint Code	L421
Contains			

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 Drug	M013	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: 11/2024

Tower Laboratories Ltd