

**TOP VALUE EFFERVESCENT COLD RELIEF- aspirin, chlorpheniramine maleate, phenylephrine bitartrate 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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**Top Value Effervescent Cold Relief**

**Purpose**

Pain reliever/fever reducer

Antihistamine

Nasal decongestant

**Active ingredients**

Aspirin 325 mg (NSAID)\*

Chlorpheniramine maleate 2 mg

Phenylephrine Bitartrate 7.8 mg

\*Nonsteroidal anti-inflammatory drug

**Uses**

temporarily relieves these symptoms of the common cold

- fever ■ sneezing ■ nasal congestion ■ sore throat ■ headache
- minor aches and pains ■ runny nose
- sinus congestion and pressure

**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

**Sore throat warning:** If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

### **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 you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before 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 are taking sedatives or tranquilizers

You have ■ glaucoma ■ diabetes ■ thyroid disease ■ trouble urinating due to an enlarged prostate gland ■ a breathing problem such as emphysema or chronic bronchitis ■ been placed on a sodium-restricted diet

### **Ask a doctor or pharmacist before use if you are**

- presently taking a prescription drug.
- 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 and children 12 years and over) in a 24-hour period or as directed by doctor.
- do not use more than directed
- you may get drowsy
- avoid alcoholic drinks
- excitability may occur, especially in children
- alcohol, sedatives and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

## **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 or nasal congestion gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present
- ringing in the ears or a loss of hearing occurs
- nervousness, dizziness or sleeplessness 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.**

## **In case of overdose,**

get medical help or contact a Poison Control Center right away.

**Keep out of reach of children.**

## **Directions**

- do not use more than directed (see overdose warning)
- adults and children 12 years and over: take 2 tablets completely dissolved in 4 ounces of water every 4-6 hours
- do not take more than 8 tablets in 24 hours
- children under 12 years: ask a doctor

## **Other information**

each tablet contains:  
sodium 464 mg

- phenylketonurics: contains phenylalanine 9 mg per tablet
- store at room temperature (59°-86°F)

## **Inactive Ingredients:**

acesulfame potassium, aspartame, citric acid, docusate sodium, flavors, mannitol, povidone, sodium benzoate, sodium bicarbonate

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



## TOP VALUE EFFERVESCENT COLD RELIEF

aspirin, chlorpheniramine maleate, phenylephrine bitartrate tablet, effervescent

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50201-7682
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ASPIRIN</b> (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 mg
<b>PHENYLEPHRINE BITARTRATE</b> (UNII: 27O3Q5ML57) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE BITARTRATE	7.8 mg
<b>CHLORPHENIRAMINE MALEATE</b> (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>ACESULFAME POTASSIUM</b> (UNII: 23OV73Q5G9)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>DOCUSATE SODIUM</b> (UNII: F05Q2T2JA0)	
<b>ASPARTAME</b> (UNII: Z0H242BBR1)	
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>MANNITOL</b> (UNII: 3OWL53L36A)	
<b>POVIDONE K30</b> (UNII: U725QWY32X)	

### 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>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50201-7682-2	10 in 1 CARTON	07/01/2010	
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	part341	07/01/2010	

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

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

### Establishment

Name	Address	ID/FEI	Business Operations
Tower Laboratories Ltd		869024500	manufacture(50201-7682) , label(50201-7682) , pack(50201-7682)

