

**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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**Drug Facts**

*Active Ingredients (in each effervescent tablet)*

Aspirin 325 mg **NSAID\***.....  
Chlorpheniramine maleate 2 mg .....  
Phenylephrine Bitartrate 7.8 mg .....

*Purpose*

Pain reliever/fever reducer  
Antihistamine  
Nasal decongestant

\*Nonsteroidal anti-inflammatory drug

**Warnings**

**Reye's syndrome:** Children and teenagers should not use this drug for chicken pox or flu symptoms before a doctor is consulted about Reye's syndrome, a rare but serious illness reported to be associated with aspirin.

**Allergy alert:** Aspirin may cause a server 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.

**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 - glaucoma - diabetes - thyroid disease - trouble urinating due to an enlarged prostate gland - a breathing problem such as emphysema or chronic bronchitis - you are taking a diuretic - 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.

**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.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

**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.

## Fast Relief of: Nasal Congestion, Runny Nose, Sneezing, Headache, Sinus Pain and Pressure

**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

**Stop use and ask a doctor if** - you experience any of the following signs of stomach bleeding - feel faint - vomit blood - have bloody 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 loss of hearing occurs - nervousness, dizziness or sleeplessness occurs.

### 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 a 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

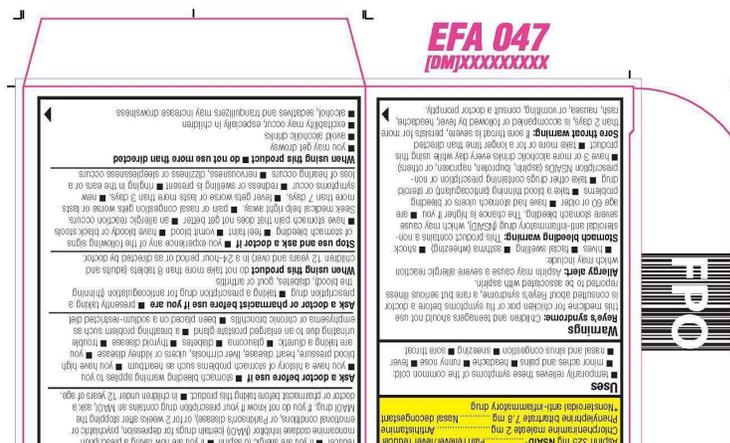
**Adverse Event Reporting:** Serious side effects associated with the use of this product can be reported to the following address or by calling the following telephone number.

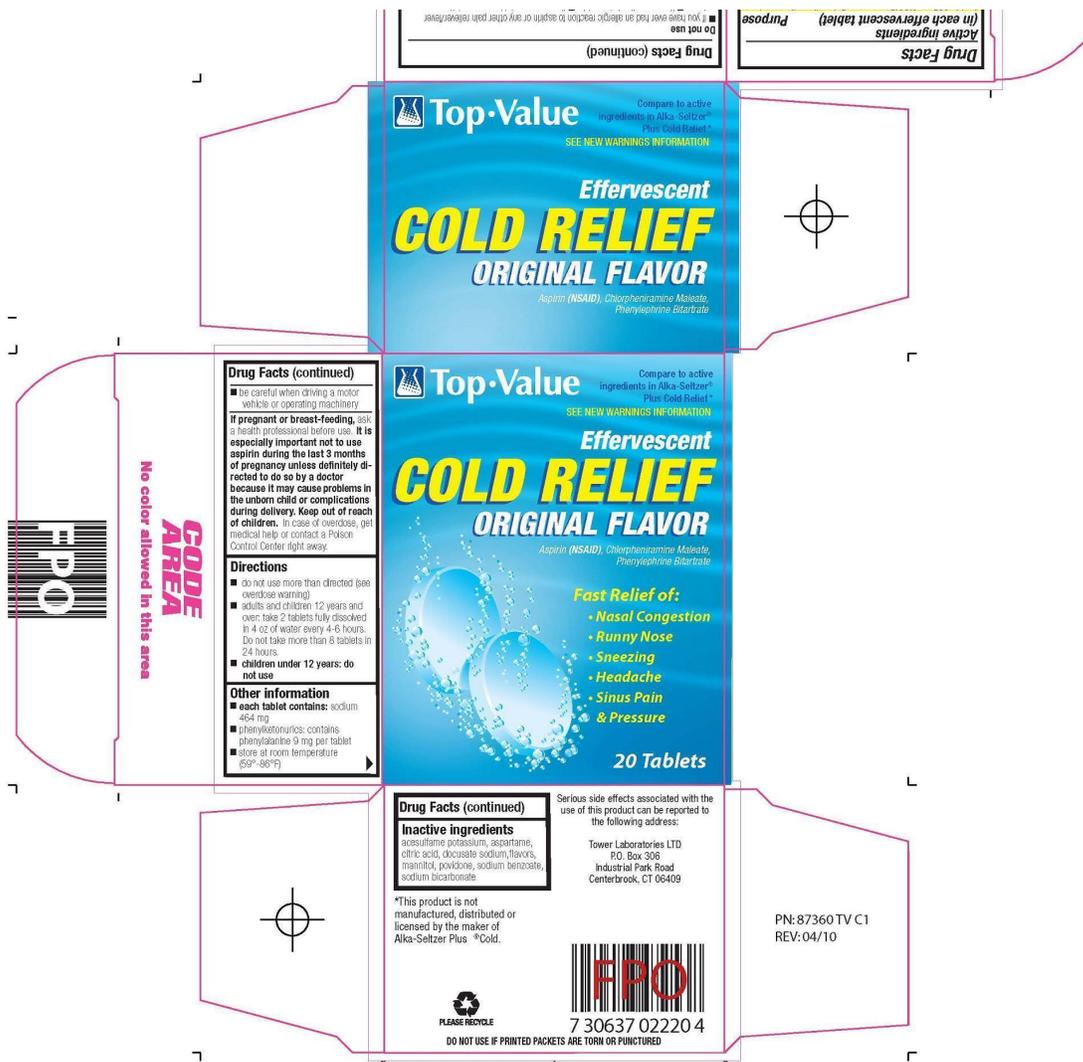
### Directions

- 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

### Inactive ingredients:

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





## EFFERVESCENT COLD RELIEF

aspirin, chlorpheniramine maleate, phenylephrine bitartrate tablet, effervescent

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50201-0246
Route of Administration	ORAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ASPARTAME (UNII: Z0H242BBR1)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
DOCUSATE SODIUM (UNII: F05Q2T2JA0)	
MANNITOL (UNII: 3OWL53L36A)	
POVIDONE K30 (UNII: U725QWY32X)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	

**Product Characteristics**

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	25mm
<b>Flavor</b>	LEMON (N&A Lemon Lime Flavor FAKP193)	<b>Imprint Code</b>	CF
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50201-0246-1	2 in 1 POUCH		

**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 (869024500)**Establishment**

Name	Address	ID/FEI	Business Operations
Tower Laboratories Ltd		869024500	manufacture(50201-0246)

