GOOD SENSE 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.

Good Sense Effervescent Cold Relief

Active ingredients

(in each effervescent tablet)

Aspirin 325 mg (NSAID)*

Chlorpheniramine maleate 2 mg

Phenylephrine bitartrate 7.8 mg

Purpose

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

^{*}Nonsteroidal anti-inflammatory drug

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

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** ■ 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

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

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 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

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

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

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- do not use more than directed (see overdose warning)
- adults and children 12 years and over: take 2 tablets completely dissolved in 4 oz 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 Rd. Centerbrook, CT 06409

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

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Drug Facts (continued)

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Pain relever/aver reducer redu Purpose

(in each effervescent tablet) Active ingredients

Drug Facts

GOODSENSE.

Effervescent

Nasal Decongestant, Antihistamine Pain Reliever/Fever Reducer

Geiss, Destin & Dunn, Inc Peachtree City, GA 30269 www.valuelabels.com 1-866-696-0957



NDC 50201-8736-0

Fast Relief Plus

Effervescent Cold Relief

Aspirin (NSAID)/Pain Reliever/Fever Reducer Chlorpheniramine Maleate/Antihistamine



FAST RELIEF OF:

- Nasal Congestion
- Runny Nose
- Sneezing
- Headache • Sinus Pain & Pressure

20 Effervescent Tablets



Directions

do not use more than directed

Drug Facts (continued)

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you may get drowsy
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Drug Facts (continued)

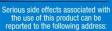
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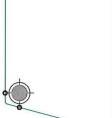
Tower Laboratories LTD.
P.O. Box 306 8 Industrial Park Rd.
Centerbrook, CT 06409

DO NOT USE IF PRINTED PACKETS ARE TORN OR PUNCTURED



PN: 87360 GS C1 REV: 08/19





GOOD SENSE EFFERVESCENT COLD RELIEF

aspirin, chlorpheniramine maleate, phenylephrine bitartrate tablet, effervescent

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50201-8736	
Route of Administration	ORAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
CHLORPHENIRAMINE MALEATE (UNII: V1Q0090J9Z) (CHLORPHENIRAMINE - UNII: 3U6I01965U)	CHLORPHENIRAMINE MALEATE	2 mg		
PHENYLEPHRINE BITARTRATE (UNII: 2703Q5ML57) (PHENYLEPHRINE - UNII: 1WS 297W6MV)	PHENYLEPHRINE BITARTRATE	7.8 mg		
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 mg		

Inactive Ingredients				
Ingredient Name	Strength			
DOCUSATE SODIUM (UNII: F05Q2T2JA0)				
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)				
ASPARTAME (UNII: Z0H242BBR1)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
POVIDONE K30 (UNII: U725QWY32X)				
SODIUM BICARBONATE (UNII: 8MDF5V39QO)				
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
MANNITOL (UNII: 30WL53L36A)				

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

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:50201- 8736-0	10 in 1 CARTON	08/15/2019		
1		2 in 1 POUCH; Type 0: Not a Combination Product			

Marketing In	formation		
Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date

OTC monograph final	part341	02/19/2013	12/31/2024

Labeler - Tower Laboratories Ltd. (001587203)

Registrant - Tower Laboratories Ltd. (001587203)

Establishment			
Name	Address	ID/FEI	Business Operations
Tower Laboratories Ltd.		869024500	manufacture(50201-8736) , pack(50201-8736) , label(50201-8736)

Revised: 12/2022 Tower Laboratories Ltd.