TOP VALUE EFFERVESCENT COLD RELIEF - ORANGE- aspirin, chlorpheniramine maleate, phenylephrine bitartrate tablet, effervescent
Tower Laboratories Ltd.

Top Value Effervescent Cold Relief Tablets - Orange

Active ingredients

(in each effervescent tablet)

Aspirin 325 mg **(NSAID)***

Chlorpheniramine maleate 2 mg

Phenylephrine bitartrate 7.8 mg

*Nonsteroidal anti-inflammatory drug

Purpose

Aspirin 325 mg (NSAID)*.....Pain reliever/fever reducer

Chlorpheniramine maleate 2 mg.....Antihistamine

Phenylephrine Bitartrate 7.8 mg.....Nasal decongestant

*Nonsteroidal anti-inflammatory drug

Uses

■ temporarily relieves these symptoms due to the common cold:

■ sneezing ■ nasal congestion ■ sore throat

■ headache ■ minor aches and pains ■ runny nose

■ sinus congestion and pressure

■ temporarily reduces fever

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 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

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. ■ if you 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

Ask a doctor before use if you have

Ask a doctor before use if you have ■ asthma ■ 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 ■ taking sedatives or tranquilizers ■ presently taking a prescription drug ■ taking a prescription drug for anticoagulation (thinning the blood), diabetes, gout or arthritis

When using this product

When using this product ■ do not exceed the recommended dosage

■ 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

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

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 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 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, anhydrous citric acid, aspartame, docusate sodium, FD&C red #40, FD&C yellow #6, flavors, mannitol, povidone, sodium benzoate, sodium

bicarbonate

Serious side effects assoicated with the use of this product can be reported to the following address:

Tower Laboratories LTD

8 Industrial Park Road

Centerbrook, CT 06409

or by calling the following:

1-888-228-6937

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

TOP VALUE EFFERVESCENT COLD RELIEF - ORANGE

aspirin, chlorpheniramine maleate, phenylephrine bitartrate tablet, effervescent

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50201-8752
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

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

Product Characteristics

Color	orange	**Score**	no score
Shape	ROUND	**Size**	25mm
Flavor		**Imprint Code**	CF
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50201-8752-0	10 in 1 CARTON	04/16/2021	
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	M012	04/16/2021	

Labeler - Tower Laboratories Ltd. (001587203)