

**QUALITY CHOICE EFFERVESCENT COLD RELIEF - ORANGE- aspirin,  
chlorpheniramine maleate, phenylephrine bitartrate tablet, effervescent  
Chain Drug Marketing Association**

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**Quality Choice Effervescent Cold Relief Plus 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

### **Questions or comments?**

**Call (1-800-935-2362)**



aspirin, chlorpheniramine maleate, phenylephrine bitartrate tablet, effervescent

## Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:63868-568 |
| <b>Route of Administration</b> | ORAL           |                           |               |

## Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength        | Strength |
|---|--------------------------|----------|
| <b>PHENYLEPHRINE BITARTRATE</b> (UNII: 27O3Q5ML57) (PHENYLEPHRINE - UNII:1WS297W6MV)    | PHENYLEPHRINE BITARTRATE | 7.8 mg   |
| <b>ASPIRIN</b> (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)                           | ASPIRIN                  | 325 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>ASPARTAME</b> (UNII: Z0H242BBR1)             |          |
| <b>MANNITOL</b> (UNII: 3OWL53L36A)              |          |
| <b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO)    |          |
| <b>DOCUSATE SODIUM</b> (UNII: F05Q2T2JA0)       |          |
| <b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)       |          |
| <b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL) |          |
| <b>POVIDONE K30</b> (UNII: U725QWY32X)          |          |

## Product Characteristics

|                 |        |                     |          |
|-----------------|--------|---------------------|----------|
| <b>Color</b>    | orange | <b>Score</b>        | no score |
| <b>Shape</b>    | ROUND  | <b>Size</b>         | 25mm     |
| <b>Flavor</b>   |        | <b>Imprint Code</b> | CF       |
| <b>Contains</b> |        |                     |          |

## Packaging

| # | Item Code        | Package Description                             | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:63868-568-20 | 10 in 1 CARTON                                  | 06/15/2020           |                    |
| 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                                     | 06/15/2020           |                    |

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**Labeler** - Chain Drug Marketing Association (011920774)

Revised: 11/2024

Chain Drug Marketing Association