

**ALKA-SELTZER PLUS COLD ORANGE ZEST- aspirin, chlorpheniramine maleate, phenylephrine bitartrate tablet, effervescent  
Bayer HealthCare LLC.**

*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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**Alka-Seltzer Plus® Cold Orange Zest Effervescent Tablets**

**Drug Facts**

**Active ingredients (in each tablet)**

Aspirin 325 mg (NSAID)\*

Chlorpheniramine maleate 2 mg

Phenylephrine bitartrate 7.8 mg

\*nonsteroidal anti-inflammatory drug

**Purposes**

Pain reliever/fever reducer

Antihistamine

Nasal decongestant

**Uses**

- temporarily relieves these symptoms due to a cold:
- minor aches and pains · headache · runny nose
- nasal and sinus congestion · sneezing · sore throat
- 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 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 to sedate children.**

**Do not use**

- if you are allergic to aspirin or any other pain reliever/fever reducer
- 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 have ever had an allergic reaction to this product or any of its ingredients
- in children under 12 years of age

**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
  - asthma ● diabetes
  - thyroid disease ● glaucoma
  - difficulty in urination due to enlargement of the prostate gland
  - a breathing problem such as emphysema or chronic bronchitis
  - a sodium-restricted diet

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

- taking a prescription drug for
- gout · diabetes · arthritis

- taking sedatives or tranquilizers

### **When using this product**

- **do not exceed recommended dosage**
- excitability may occur, especially in children
- you may get drowsy
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

### **Stop use and ask a doctor if**

- an allergic reaction occurs. Seek medical help right away.
- 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
- pain or nasal congestion gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- ringing in the ears or a loss of hearing occurs
- nervousness, dizziness, or sleeplessness occur

**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***

- adults and children 12 years and over: take 2 tablets fully dissolved in 4 oz of water every 4 hours. Do not exceed 8 tablets in 24 hours or as directed by a doctor.
- children under 12 years: do not use

### ***Other information***

- each tablet contains: sodium 476 mg
- Phenylketonurics: Contains Phenylalanine 9 mg Per Tablet
- store at room temperature. Avoid excessive heat.

**Inactive ingredients** acesulfame potassium, anhydrous citric acid, aspartame, calcium silicate, dimethicone, docusate sodium, FD&C red #40, FD&C yellow #6, flavors, mannitol, povidone, sodium benzoate, sodium bicarbonate

**Questions or comments?** 1-800-986-0369 (Mon - Fri 9AM - 5PM EST)

ALka-

Seltzer®

PLUS

Cold

ORANGE ZEST

ASPIRIN (**NSAID**)/Pain Reliever-Fever Reducer

Chlorpheniramine Maleate/Antihistamine

Phenylephrine Bitartrate/Nasal Decongestant

- Nasal Congestion
- Runny Nose
- Sore Throat
- Headache & Body Ache
- Sinus Pressure

20 EFFERVESCENT TABLETS



## ALKA-SELTZER PLUS COLD ORANGE ZEST

aspirin, chlorpheniramine maleate, phenylephrine bitartrate tablet, effervescent

### Product Information

#### Product Type

HUMAN OTC DRUG

#### Item Code (Source)

NDC:0280-1510

#### Route of Administration

ORAL

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>CALCIUM SILICATE</b> (UNII: S4255P4G5M)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>ACESULFAME POTASSIUM</b> (UNII: 23OV73Q5G9)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>DOCUSATE SODIUM</b> (UNII: F05Q2T2JA0)	
<b>MANNITOL</b> (UNII: 3OWL53L36A)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO)	

## Product Characteristics

<b>Color</b>	white (White with orange and black flecks)	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	25mm
<b>Flavor</b>	ORANGE	<b>Imprint Code</b>	Alka;Seltzer
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0280-1510-20	10 in 1 CARTON	07/15/2017	
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	07/15/2017	

Revised: 11/2022

Bayer HealthCare LLC.