

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

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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

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0280-1510
<b>Route of Administration</b>	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 Drug	M012	07/15/2017	

Revised: 12/2023

Bayer HealthCare LLC.