

**ALKA-SELTZER PLUS SEVERE COLD POWERFAST FIZZ NON DROWSY- aspirin, dextromethorphan hydrobromide, phenylephrine bitartrate tablet, effervescent**  
**Bayer HealthCare LLC.**

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**Alka-Seltzer Plus Severe Cold PowerFast Fizz Non Drowsy Effervescent Tablets UI1614460**

***Drug Facts***

**Active ingredients**

***Active ingredients (in each tablet) Purposes***

Aspirin 325 mg (NSAID)\*.....Pain reliever/fever reducer  
Dextromethorphan hydrobromide 10 mg.....Cough suppressant  
Phenylephrine bitartrate 7.8 mg.....Nasal decongestant

\*nonsteroidal anti-inflammatory drug

**Uses**

***Uses***

- temporarily relieves these symptoms due to a cold with cough:
- minor aches and pains · headache · cough
- nasal and sinus congestion · sore throat
- temporarily reduces fever

**Warnings**

***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**

#### **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**

#### **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
  - thyroid disease
  - diabetes
- cough with excessive phlegm (mucus)
- difficulty in urination due to enlargement of the prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- a sodium-restricted diet

## **Ask a doctor or pharmacist**

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

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

## **When using this product**

### **When using this product do not exceed recommended dosage**

## **Stop use**

### **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, cough, 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
- cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.
- nervousness, dizziness, or sleeplessness occurs

## **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**

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

## **Directions**

### ***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**

### ***Other information***

- **each tablet contains:** potassium 80 mg; sodium 356 mg
- store at room temperature. Avoid excessive heat.

## **Inactive ingredients**

***Inactive ingredients*** anhydrous citric acid, calcium silicate, dimethicone, FD&C red #40, FD&C yellow #6, flavor, mannitol, potassium bicarbonate, povidone, sodium bicarbonate, sucralose

## **Questions**

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

## **Carton 20 count**

Alka-Seltzer Plus®

SEVERE

Cold

CITRUS

POWERFAST™ FIZZ

NEW IMPROVED FLAVOR

NON-DROWSY

ASPIRIN (NSAID) / Pain Reliever-Fever Reducer

Dextromehorphan HBr / Cough Suppressant

Phenylephrine Bitartrate / Nasal Decongestant

- Fever + Body Ache
- Nasal Congestion
- Sinus Pressure
- Sore Throat
- Cough

20 EFFERVESCENT TABLETS

**INSIDE "LIFT HERE" FLAP**

<b>Drug Facts (continued)</b>	
<ul style="list-style-type: none"> <li>• you have</li> <li>• asthma</li> <li>• cough with excessive phlegm (mucus)</li> <li>• difficulty in urination due to enlargement of the prostate gland</li> <li>• persistent or chronic cough such as occurs with smoking, asthma, or emphysema</li> <li>• a sodium restricted diet</li> </ul>	<ul style="list-style-type: none"> <li>• thyroid disease</li> <li>• diabetes</li> </ul>
<p><b>Ask a doctor or pharmacist before use if you are</b></p> <ul style="list-style-type: none"> <li>• taking a prescription drug for</li> <li>• gout</li> <li>• diabetes</li> <li>• arthritis</li> </ul>	
<p><b>When using this product do not exceed recommended dosage</b></p>	
<p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>• an allergic reaction occurs. Seek medical help right away.</li> <li>• you experience any of the following signs of stomach bleeding:             <ul style="list-style-type: none"> <li>• feel faint</li> <li>• vomit blood</li> <li>• have bloody or black stools</li> </ul> </li> <li>• have stomach pain that does not get better</li> <li>• pain, cough, or nasal congestion gets worse or lasts more than 7 days</li> <li>• fever gets worse or lasts more than 3 days</li> <li>• redness or swelling is present</li> <li>• new symptoms occur</li> <li>• ringing in the ears or a loss of hearing occurs</li> <li>• cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.</li> <li>• nervousness, dizziness, or sleeplessness occurs</li> </ul>	
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**Drug Facts (continued)**

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

**19344**

**Alka-Seltzer PLUS Cold**

**SEVERE**

**CITRUS**

**POWER FAST FIZZ**

**NON-DROWSY**

**PARENTS:**  
Learn about teen medicine abuse  
[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)

**19344**



## ALKA-SELTZER PLUS SEVERE COLD POWERFAST FIZZ NON DROWSY

aspirin, dextromethorphan hydrobromide, phenylephrine bitartrate tablet, effervescent

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0280-0024
<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>PHENYLEPHRINE BITARTRATE</b> (UNII: 2703Q5ML57) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE BITARTRATE	7.8 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>MANNITOL</b> (UNII: 3OWL53L36A)	
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO)	
<b>CALCIUM SILICATE</b> (UNII: S4255P4G5M)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>POTASSIUM BICARBONATE</b> (UNII: HM5Z15LEBN)	

## Product Characteristics

<b>Color</b>	white (Speckled)	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	25mm
<b>Flavor</b>	CITRUS	<b>Imprint Code</b>	ASP
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0280-0024-01	10 in 1 CARTON	04/30/2020	
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:0280-0024-02	24 in 1 CARTON	07/01/2022	
2		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	04/01/2020	

**Labeler** - Bayer HealthCare LLC. (112117283)