

**ALKA-SELTZER PLUS SEVERE COLD AND FLU POWERFAST FIZZ-  
chlorpheniramine maleate, acetaminophen, phenylephrine hydrochloride,  
dextromethorphan hydrobromide 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 Severe Cold & Flu PowerFast Fizz UI 1614461**

**Drug Facts**

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

Acetaminophen 250 mg.....Pain reliever/fever reducer  
Chlorpheniramine maleate 2 mg.....Antihistamine  
Dextromethorphan hydrobromide 10 mg.....Cough suppressant  
Phenylephrine hydrochloride 5 mg.....Nasal decongestant

**Uses**

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

**Warnings**

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

**Allergy alert:** Acetaminophen may cause severe skin or severe allergic reactions. Symptoms may include:

- skin reddening · blisters · rash · hives
- facial swelling · asthma (wheezing) · shock

If a skin or general allergic reaction occurs, stop use and seek medical help right away.

**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**

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- 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 you have**

- liver disease ● heart disease ● high blood pressure
- thyroid disease ● diabetes ● glaucoma
- cough with excessive phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis
- 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 before use if you are**

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

### **When using this product**

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

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

- 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
- cough comes back or occurs with rash or headache that lasts.

These could be signs of a serious condition.

- nervousness, dizziness, or sleeplessness occurs

**If pregnant or breast-feeding**, ask a health professional before use.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms

## **Directions**

### ***Directions***

- do not take more than the recommended dose
- 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:** potassium 80 mg; sodium 356 mg
- store at room temperature. Avoid excessive heat.

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

## **Questions or comments**

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

Alka-Seltzer®

PLUS

SEVERE

Cold

& Flu

CITRUS

POWERFAST FIZZ™

NEW IMPROVED FLAVOR

**ACETAMINOPHEN/Pain Reliever-Fever Reducer**

Chlorpheniramine Maleate/Antihistamine

Dextromethorphan HBr/ Cough Suppressant

Phenylephrine Hydrochloride/Nasal Decongestant

- Fever & Body Ache
- Cough
- Nasal Congestion
- Runny Nose
- Sore Throat

20 EFFERVESCENT TABLETS



## ALKA-SELTZER PLUS SEVERE COLD AND FLU POWERFAST FIZZ

chlorpheniramine maleate, acetaminophen, phenylephrine hydrochloride, dextromethorphan hydrobromide tablet, effervescent

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:0280-0022

<b>Route of Administration</b>	ORAL
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### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
<b>CHLORPHENIRAMINE MALEATE</b> (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>CALCIUM SILICATE</b> (UNII: S4255P4G5M)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>MANNITOL</b> (UNII: 3OWL53L36A)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>POTASSIUM BICARBONATE</b> (UNII: HM5Z15LEBN)	
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO)	

### Product Characteristics

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0280-0022-01	10 in 1 CARTON	04/01/2020	
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:0280-0022-02	36 in 1 CARTON	09/15/2021	
2		2 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:0280-0022-03	3200 in 1 BOX	02/01/2022	
3		1 in 1 BOX; Type 0: Not a Combination		

3		Product		
4	NDC:0280-0022-04	24 in 1 CARTON	03/09/2022	
4		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	04/01/2020	

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

Revised: 4/2022

Bayer HealthCare LLC.