

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

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**Alka-Selzer Plus Severe Cold PowerFast Fizz Night effervescent tablets UI 1614897**

***Drug Facts***

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

Aspirin 325 mg (NSAID)\*.....Pain reliever/fever reducer  
Dextromethorphan hydrobromide 10 mg.....Cough suppressant  
Doxylamine succinate 6.25 mg.....Antihistamine  
Phenylephrine bitartrate 7.8 mg.....Nasal decongestant

\*nonsteroidal anti-inflammatory drug

***Uses***

- temporarily relieves these symptoms due to a cold:
  - minor aches and pains
  - headache
  - runny nose
  - sinus congestion and pressure
  - cough
  - sneezing
  - sore throat
  - nasal congestion
- 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
    - cough that occurs 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 a prescription drug for
  - gout
  - diabetes
  - arthritis
- 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**

- 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

**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 of age: do not use

**Other information**

- **each tablet contains:** potassium 78 mg; sodium 356 mg
- store at room temperature. Avoid excessive heat.

**Inactive ingredients** anhydrous citric acid, calcium silicate, dimethicone, flavors, mannitol, potassium bicarbonate, povidone, sodium bicarbonate, sucralose

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

**Carton 20 count**

Alka-Seltzer Plus®

**SEVERE**

**Cold**

LEMON

POWERFAST FIZZ™ SEE NEW DOSING DIRECTIONS

NIGHT

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

Dextromethorphan HBr / Cough Suppressant

Doxylamine Succinate / Antihistmine

Phenylephrine Bitartrate / Nasal Decongestant

- Nasal Congestion
- Headache + Body Ache
- Cough
- Runny Nose
- Sore Throat

20 EFFERVESCENT TABLETS



## ALKA-SELTZER PLUS SEVERE COLD NIGHT POWERFAST FIZZ

aspirin, doxylamine succinate, dextromethorphan hydrobromide, phenylephrine bitartrate tablet, effervescent

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0280-0068
<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>DOXYLAMINE SUCCINATE</b> (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
<b>PHENYLEPHRINE BITARTRATE</b> (UNII: 27O3Q5ML57) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE BITARTRATE	7.8 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>CALCIUM SILICATE</b> (UNII: S4255P4G5M)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>MANNITOL</b> (UNII: 3OWL53L36A)	
<b>POTASSIUM BICARBONATE</b> (UNII: HM5Z15LEBN)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	25mm
<b>Flavor</b>	LEMON	<b>Imprint Code</b>	ASP;NT
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0280-0068-01	10 in 1 CARTON	07/12/2021	
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	07/12/2021	

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

Revised: 12/2023

Bayer HealthCare LLC.