**ALKA-SELTZER PLUS SEVERE COLD POWERFAST FIZZ DAY AND NIGHT- aspirin, dextromethorphan hydrobromide, phenylephrine bitartrate**
**Bayer HealthCare LLC.**

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**Alka-Seltzer Plus Severe Cold PowerFast Fizz Day and Night Effervescent Tablets UI 1614460 & 161897**

***Drug Facts***

**Alka-Seltzer Plus® Severe Cold PowerFast Fizz Day Effervescent Tablets**

***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***

- temporarily relieves these symptoms due to a cold with cough:
  - minor aches and pains
  - headache
  - sinus congestion and pressure
  - cough
  - 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**

● 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 itsingredients

● 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 •thyroid •disease diabetes
  - cough that occurs 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 before use if you are**

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

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

**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 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***

- do not take more than the recommended dose
- do not take the Day and Night products at the same time; wait 4 hours after taking the last Night dose before taking the Day product
- adults and children 12 years and over: take 2 tablets fully dissolved in 4 oz of water every 4 hours. Do not exceed 4 tablets in 12 hours or as directed by a doctor.
- children under 12 years: 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, FD&C red #40, FD&C yellow #6, flavor, mannitol, potassium bicarbonate, povidone, sodium bicarbonate, sucralose

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

**Alka-Seltzer Plus® Cold PowerFast Fizz Night Effervescent Tablets**

***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
- artake 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 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***

- do not take more than the recommended dose
- do not take the Day and Night products at the same time; wait 4 hours after taking the last Day dose before taking the Night product
- adults and children 12 years and over: take 2 tablets fully dissolved in 4 oz of water

every 4 hours. Do not exceed 4 tablets in 12 hours or as directed by a doctor.
- children under 12 years: 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)

Alka-Seltzer Plus®

SEVERE COLD

DAY/CITRUS

NIGHT LEMON

POWERFAST FIZZ™

DAY NON-DROWSY

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

DEXTROMETHORPHAN HBr/Cough Suppressant

PHENYLEPHRINE BITARTRATE/Nasal Decongestant

- Nasal Decongestant
- Headache + Body Ache
- Cough
- Sore Throat
- Sinus Pressure

12 EFFERVESCENT TABLETS

**NEW NIGHT DOSING DIRECTIONS**

NIGHT

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

Dextromethorphan HBr/Cough Suppressant

Doxylamine Succinate/Antihistamine

Phenylephrine Bitartrate/Nasal Decongestant
- Nasal congestion
- Headache + Body Ache
- Cough
- Runny Nose
- Sore Throat

8 EFFERVESCENT TABLETS


# ALKA-SELTZER PLUS SEVERE COLD POWERFAST FIZZ DAY AND NIGHT

aspirin, dextromethorphan hydrobromide, phenylephrine bitartrate kit

## Product Information

| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0280-0086 |
|---|---|---|---|

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| 1 | NDC:0280-0086-01 | 1 in 1 CARTON; Type 0: Not a Combination Product | 04/29/2022 | |

## Quantity of Parts

| Part # | Package Quantity | Total Product Quantity |
|---|---|---|
| Part 1 | 32 POUCH | 32 |
| Part 2 | 16 POUCH | 16 |

## Part 1 of 2

# ALKA-SELTZER PLUS SEVERE COLD POWERFAST FIZZ NON DROWSY

asprin, dextromethorphan hydrobromide, phenylephrine bitartrate tablet, effervescent

| Product Information | |
|---|---|
| **Item Code (Source)** | NDC:00280-0020 |
| **Route of Administration** | ORAL |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **ASPIRIN** (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E) | ASPIRIN | 325 mg |
| **DEXTROMETHORPHAN HYDROBROMIDE** (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 10 mg |
| **PHENYLEPHRINE BITARTRATE** (UNII: 27O3Q5ML57) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE BITARTRATE | 7.8 mg |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **ANHYDROUS CITRIC ACID** (UNII: XF417D3PSL) | |
| **MANNITOL** (UNII: 3OWL53L36A) | |
| **POTASSIUM BICARBONATE** (UNII: HM5Z15LEBN) | |
| **POVIDONE** (UNII: FZ989GH94E) | |
| **SODIUM BICARBONATE** (UNII: 8MDF5V39QO) | |
| **CALCIUM SILICATE** (UNII: S4255P4G5M) | |
| **FD&C RED NO. 40** (UNII: WZB9127XOA) | |
| **FD&C YELLOW NO. 6** (UNII: H77VEI93A8) | |
| **SUCRALOSE** (UNII: 96K6UQ3ZD4) | |
| **DIMETHICONE** (UNII: 92RU3N3Y1O) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | white | **Score** | no score |
| **Shape** | ROUND | **Size** | 25mm |
| **Flavor** | CITRUS | **Imprint Code** | ASP |
| **Contains** | | | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | | 1 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 | 04/29/2022 | |

## Part 2 of 2

# ALKA-SELTZER PLUS SEVERE COLD NIGHT POWERFAST FIZZ

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

### Product Information

| | |
|---|---|
| **Item Code (Source)** | NDC:0280-0068 |
| **Route of Administration** | ORAL |

### Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **DOXYLAMINE SUCCINATE** (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL) | DOXYLAMINE SUCCINATE | 6.25 mg |
| **DEXTROMETHORPHAN HYDROBROMIDE** (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 10 mg |
| **ASPIRIN** (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E) | ASPIRIN | 325 mg |
| **PHENYLEPHRINE BITARTRATE** (UNII: 27O3Q5ML57) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE BITARTRATE | 7.8 mg |

### Inactive Ingredients

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

### Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | white | **Score** | no score |
| **Shape** | ROUND | **Size** | 25mm |
| **Flavor** | LEMON | **Imprint Code** | ASP;NT |
| **Contains** | | | |

| Packaging | | | | |
|---|---|---|---|---|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | | 1 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 | 04/29/2022 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC Monograph Drug | M012 | 04/27/2022 | |

## Labeler - Bayer HealthCare LLC. (112117283)

Revised: 12/2023 Bayer HealthCare LLC.