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

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**
MANNITOL (UNII: 3OWL53L36A)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
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)

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