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

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

Drug Facts (continued)

- 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 before use if you are

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

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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
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asprin, dextromethorphan hydrobromide, phenylephrine bitartrate tablet, effervescent

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0280-0024
Route of Administration	ORAL		

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

Inactive Ingredients

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

Product Characteristics

Color	white (Speckled)	**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	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)

Revised: 12/2023 Bayer HealthCare LLC.