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

Alka-Seltzer Plus Severe Cold Powerfast Fizz UI 1614458

Drug Facts

Active ingredients (in each tablet) Purposes

Aspirin 500 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

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 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

Directions

● adults and children 12 years and over: take 2 tablets fully dissolved

in 4 oz of water every 6 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 anhydrous citric acid, calcium silicate, dimethicone, flavors, 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

POWERFAST FIZZ™ NEW IMPROVED FLAVOR

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

20 EFFERVESCENT TABLETS

ALKA-SELTZER PLUS SEVERE COLD POWERFAST FIZZ NIGHT

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

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0280-0021
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	500 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
PHENYLEPHRINE BITARTRATE (UNII: 27O3Q5ML57) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE BITARTRATE	7.8 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

Inactive Ingredients

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

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	NDC:0280-0021-01	10 in 1 CARTON	04/01/2020	
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	04/01/2020	

Labeler - Bayer HealthCare LLC. (112117283)

Revised: 12/2023 Bayer HealthCare LLC.