ALKA-SELTZER PLUS COLD SPARKLING ORIGINAL POWERFAST FIZZ- aspirin, chlorpheniramine maleate, phenylephrine bitartrate tablet, effervescent
Bayer HealthCare LLC.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

ASP Severe Cold Sparkling Original PowerFast Fizz UI1614456

Drug Facts

Active ingredients (in each tablet) Purposes

Aspirin 325 mg (NSAID)*.....Pain reliever/fever reducer

Chlorpheniramine maleate 2 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
- nasal congestion
- sneezing
- sore throat
- sinus congestion and pressure

temporarily reduces fever

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

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

● difficulty in urination due to enlargement of the prostate gland

● a breathing problem such as emphysema or chronic bronchitis

● 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

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taking a prescription drug for
- gout
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If pregnant or breast-feeding, ask a health professional before use.

It is especially important not to use aspirin at 20 weeks or later in 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: do not use

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

Alka-Seltzer Plus®

Severe Cold

Sparkling Original

POWERFAST FIZZ™

NEW LESS RESIDUE

ASPIRIN (NSAID)/Pain Reliever-Fever Reducer

Chlorpheniramine Maleate/Antihistamine

Phenylephrine Bitartrate/Nasal Decongestant

- Nasal Congestion
- Runny Nose
- Sore Throat
- Headache + Body Ache
- Sinus Pressure

24 EFFERVESCENT TABLETS

ALKA-SELTZER PLUS COLD SPARKLING ORIGINAL POWERFAST FIZZ

aspirin, chlorpheniramine maleate, phenylephrine bitartrate tablet, effervescent

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0280-0060
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 mg
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 mg
PHENYLEPHRINE BITARTRATE (UNII: 27O3Q5ML57) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE BITARTRATE	7.8 mg

Inactive Ingredients

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

Product Characteristics

Color	white	**Score**	no score
Shape	ROUND	**Size**	25mm
Flavor	LEMON	**Imprint Code**	ALKA;SELTZERplus
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0280-0060-01	10 in 1 CARTON	06/15/2021	
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:0280-0060-02	18 in 1 CARTON	06/15/2021	
2		2 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:0280-0060-03	2 in 1 CARTON	04/01/2022	
3		2 in 1 POUCH; Type 0: Not a Combination Product		
4	NDC:0280-0060-04	12 in 1 CARTON	03/30/2023	
4		2 in 1 POUCH; Type 0: Not a Combination Product		
5	NDC:0280-0060-05	2 in 1 POUCH; Type 0: Not a Combination Product	06/15/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/15/2021	

Labeler - Bayer HealthCare LLC. (112117283)

Revised: 8/2023 Bayer HealthCare LLC.