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

Alka-Seltzer Plus ® Cold Medicine Sparkling Original

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:
- 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
  - 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

When using this product

- **do not exceed recommended dosage**
- excitability may occur, especially in children
- you may get drowsy
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

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 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
- 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

- 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:** sodium 474 mg
- Phenylketonurics: Contains Phenylalanine 8.4 mg Per Tablet
- store at room temperature. Avoid excessive heat.

Inactive ingredients

acesulfame potassium, anhydrous citric acid, aspartame, calcium silicate, dimethylpolysiloxane, docusate sodium, flavors, mannitol, povidone, sodium benzoate, sodium bicarbonate

Questions or comments?

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

Dist. by: Bayer HealthCare LLC
Whippany, NJ 07981

PRINCIPAL DISPLAY PANEL - 36 Tablet Carton

Alka-
Seltzer
PLUS ®
Aspirin ***(NSAID)*** */ Pain reliever-*
fever reducer • Chlorpheniramine
maleate / Antihistamine • Phenylephrine
bitartrate / Nasal decongestant

COLD
FORMULA

SPARKLING
ORIGINAL

Nasal Congestion • Runny Nose
Headache & Body Ache
Sore Throat • Sinus Pressure

36 EFFERVESCENT TABLETS

Drug Facts

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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 and sinus congestion
  - sneezing
  - sore throat
- 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.

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Drug Facts (continued)

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Alka-Seltzer PLUS®
Aspirin (NSAID) / Pain reliever-fever reducer • Chlorpheniramine maleate / Antihistamine • Phenylephrine bitartrate / Nasal decongestant

COLD FORMULA

SPARKLING ORIGINAL

Nasal Congestion
Runny Nose
Headache & Body Ache
Sore Throat
Sinus Pressure

Lot: Expiry Date:

Dist. by: Bayer HealthCare LLC
Whippany, NJ 07981

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Drug Facts (continued)

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Bayer

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aspirin, chlorpheniramine maleate, and phenylephrine bitartrate tablet, effervescent

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0280-1400
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
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ASPARTAME (UNII: Z0H242BBR1)	
CALCIUM SILICATE (UNII: S4255P4G5M)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DOCUSATE SODIUM (UNII: F05Q2T2JA0)	
MANNITOL (UNII: 3OWL53L36A)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	

Product Characteristics

Color	white	**Score**	no score
Shape	ROUND	**Size**	25mm

Flavor		**Imprint Code**	ALKA;SELTZER;PLUS
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0280-1400-12	6 in 1 CARTON	04/10/2008	09/01/2011
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:0280-1400-20	10 in 1 CARTON	04/10/2008	06/01/2019
2		2 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:0280-1400-32	16 in 1 CARTON	04/10/2008	
3		2 in 1 POUCH; Type 0: Not a Combination Product		
4	NDC:0280-1400-36	18 in 1 CARTON	04/10/2008	06/01/2019
4		2 in 1 POUCH; Type 0: Not a Combination Product		
5	NDC:0280-1400-48	24 in 1 CARTON	06/10/2008	06/01/2019
5		2 in 1 POUCH; Type 0: Not a Combination Product		
6	NDC:0280-1400-72	36 in 1 CARTON	04/10/2008	12/01/2019
6		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	M013	04/10/2008	

Labeler - Bayer HealthCare LLC. (112117283)

Revised: 12/2023 Bayer HealthCare LLC.