

ALKA-SELTZER PLUS COLD MEDICINE SPARKLING ORIGINAL- aspirin, chlorpheniramine maleate, and 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.

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

Bayer

Drug Facts (continued)

Other Information

- each tablet contains: sodium 474 mg
- Phenylephrine: Contains Phenylephrine 8.4 mg
- Per Tablet
- store at room temperature. Avoid excessive heat.

Inactive ingredients acetylsalicylic acid, aspirin, calcium silicate, dimethylpolysiloxane, docusate sodium, flavors, mannitol, polydextrose, sodium benzoate, sodium bicarbonate

Questions or comments? 1-800-986-0369 (Mon-Fri 9AM - 5PM EST)

MADE IN MEXICO



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Warnings

- Have a 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 your 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: ● asthma (wheezing) ● hives ● facial swelling ● 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 other drugs containing aspirin or steroid drug
- take a blood thinning (anticoagulant) or steroid drug
- 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

Active ingredients (in each tablet)

Aspirin 325 mg (NSAID)
 Chlorpheniramine maleate 2 mg
 Phenylephrine bitartrate 7.8 mg
 Pain reliever/fever reducer
 Antihistamine
 Nasal decongestant

Purposes

- temporarily relieves these symptoms due to a cold: ● minor aches and pains ● headache ● stuffy nose ● runny nose ● nasal and sinus congestion ● sneezing
- temporarily reduces fever

Drug Facts (continued)

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 certain conditions)
- if you do not know if you are taking a 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

- 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 ● diabetes ● asthma ● 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 ● arthritis ● gout ● diabetes ● taking sedatives or tranquilizers

Drug Facts (continued)

When using this product

- do not exceed recommended dosage
- do not exceed recommended dosage in children
- you may get drowsy
- avoid alcoholic drinks
- do not drink
- drowsiness
- 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 certain conditions)
- if you do not know if you are taking a 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

- 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 ● diabetes ● asthma ● thyroid disease ● glaucoma ● difficulty in urination due to enlargement of the prostate gland
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Ask a doctor or pharmacist before use if you are

- taking a prescription drug for ● arthritis ● gout ● diabetes ● taking sedatives or tranquilizers

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

Exp. Date

Lot

SPARKLING ORIGINAL FORMULA

COLD

Aika-Seltzer PLUS

Aspirin (NSAID) / Pain reliever- fever reducer
 Chlorpheniramine
 Phenylephrine
 Maleate / Nasal decongestant

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

Dist. by: Bayer Healthcare LLC
 Whippany, NJ 07981
 Bayer, the Bayer Cross and Aika-Seltzer Plus are registered trademarks of Bayer.

COLD FORMULA

Aika-Seltzer PLUS

SPARKLING ORIGINAL
36 EFFERVESCENT TABLETS
Do not use if pouch is torn or open



Aika-Seltzer PLUS

Aspirin (NSAID) / Pain reliever- fever reducer
 Chlorpheniramine
 Phenylephrine

FREE VARN

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FINISH AREA



ALKA-SELTZER PLUS COLD MEDICINE SPARKLING ORIGINAL

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 not final	part343	04/10/2008		

Labeler - Bayer HealthCare LLC. (112117283)

Revised: 11/2022

Bayer HealthCare LLC.