ALKA-SELTZER PLUS COLD AND COUGH- aspirin, chlorpheniramine maleate, dextromethorphan hydrobromide, phenylephrine bitartrate tablet, effervescent
Bayer HealthCare LLC.

Alka-Seltzer Plus® Cold & Cough Effervescent Tablets

Drug Facts

Active ingredients (in each tablet)

Aspirin 325 mg (NSAID)*

Chlorpheniramine maleate 2 mg

Dextromethorphan hydrobromide 10 mg

Phenylephrine bitartrate 7.8 mg

*nonsteroidal anti-inflammatory drug

Purposes

Pain reliever/fever reducer

Antihistamine

Cough suppressant

Nasal decongestant

Uses

Uses

 temporarily relieves these symptoms due to a cold with cough:

 ·minor aches and pains ·headache ·cough

 ·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.

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

When using this product

● do not exceed recommended dosage
 may cause marked drowsiness
● avoid alcoholic drinks
● excitability may occur, especially in children
● alcohol, sedatives, and tranquilizers may increase drowsiness
● be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

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 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:** sodium 416 mg

● Phenylketonurics: Contains Phenylalanine 9 mg Per Tablet

● store at room temperature. Avoid excessive heat.

Inactive ingredients acesulfame potassium, anhydrous citric acid, aspartame, calcium silicate, dimethicone, docusate sodium, FD&C red #40, flavors, mannitol, povidone, sodium benzoate, sodium bicarbonate

Questions or comments?

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

Alka-Seltzer

PLUS®

Cold &

Cough

CITRUS

ASPIRIN **(NSAID)** / Pain Reliever/Fever Reducer

Chlorpheniramine Maleate/Antihistamine

Dextromethorphan HBr/Cough Suppresant

Phenylephrine Bitartrate/Nasal Decongestant

- Cough
- Nasal Congestion
- Runny Nose

- Headache & Body Ache
- Sinus Pressure

20 EFFERVESCENT TABLETS

ALKA-SELTZER PLUS COLD AND COUGH

aspirin, chlorpheniramine maleate, dextromethorphan hydrobromide, phenylephrine bitartrate tablet, effervescent

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0280-1555
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
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
PHENYLEPHRINE BITARTRATE (UNII: 27O3Q5ML57) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE BITARTRATE	7.8 mg

Inactive Ingredients	
Ingredient Name	**Strength**
DIMETHICONE (UNII: 92RU3N3Y1O)	

SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
DOCUSATE SODIUM (UNII: F05Q2T2JA0)	
MANNITOL (UNII: 3OWL53L36A)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
CALCIUM SILICATE (UNII: S4255P4G5M)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ASPARTAME (UNII: Z0H242BBR1)	

Product Characteristics

Color	white	**Score**	no score
Shape	ROUND	**Size**	25mm
Flavor	CITRUS	**Imprint Code**	ASP;CandC
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0280-1555-20	10 in 1 CARTON	09/14/2018	
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	09/14/2018	

Labeler - Bayer HealthCare LLC. (112117283)

Revised: 12/2023 Bayer HealthCare LLC.