

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

Alka-Seltzer Plus® Cold Night Effervescent Tablets

Drug Facts

Active ingredients (in each tablet)

Aspirin 500 mg (NSAID)*

Dextromethorphan hydrobromide 10 mg

Doxylamine succinate 6.25 mg

Phenylephrine bitartrate 7.8 mg

*nonsteroidal anti-inflammatory drug

Purposes

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Nasal decongestant

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 at bedtime (may be taken every 4 to 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:** sodium 476 mg
- Phenylketonurics: Contains Phenylalanine 5.6 mg Per Tablet
- store at room temperature. Avoid excessive heat.

Inactive ingredients acesulfame potassium, anhydrous citric acid, aspartame, calcium silicate, dimethicone, docusate sodium, flavors (natural & artificial), 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

Night

Lemon

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 COLD NIGHT

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0280-1545
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: 9D2RT9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
DOXYLAMINE SUCCINATE (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
PHENYLEPHRINE BITARTRATE (UNII: 27O3Q5ML57) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE BITARTRATE	7.8 mg

Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE (UNII: 92RU3N3Y1O)	
DOCUSATE SODIUM (UNII: F05Q2T2JA0)	

ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)
ASPARTAME (UNII: Z0H242BBR1)
CALCIUM SILICATE (UNII: S4255P4G5M)
POVIDONE (UNII: FZ989GH94E)
SODIUM BICARBONATE (UNII: 8MDF5V39QO)
MANNITOL (UNII: 3OWL53L36A)
SODIUM BENZOATE (UNII: OJ245FE5EU)

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:0280-1545-20	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)