

- 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

- 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 thyroid disease diabetes
- cough with excessive phlegm (mucus)
- 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
When using this product do not exceed recommended dosage
Stop use and ask a doctor if
<ul> <li>an allergic reaction occurs. Seek medical help right away.</li> </ul>
<ul> <li>you experience any of the following signs of stomach bleeding</li> </ul>
<ul> <li>feel faint ● vomit blood ● have bloody or black stools</li> </ul>
<ul> <li>have stomach pain that does not get better</li> </ul>
<ul><li>pain, cough, or nasal congestion gets worse or lasts more than 7 days</li></ul>
□ fever gets worse or lasts more than 3 days
□ edness or swelling is present
□ ew symptoms occur
□   ringing in the ears or loss of hearing occurs
$\hfill lackbox{\hfill} \bullet$ cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.
□ onervousness, 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, flavors, mannitol, povidone, sodium benzoate, sodium bicarbonate Questions or comments? 1-800-986-0369 (Mon – Fri 9AM – 5PM EST)

# Alka-Seltzer Plus® Cold Night Effervescent Tablets SPL

#### 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:
$\square$ • minor aches and pains $\square$ • headache $\square$ • runny nose
$\hfill \square$ • sinus congestion and pressure $\hfill \square$ • cough $\hfill \square$ • sneezing
<ul><li>□ • sore throat □ • nasal congestion</li></ul>
↑ 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:

- lacktriangle hives  $\Box$  lacktriangle facial swelling  $\Box$  lacktriangle asthma (wheezing)  $\Box$  lacktriangle 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
   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 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)

# Package Display Label

Alka-Seltzer

**PLUS®** 

**DAY NON-DROWSY** 

ASPIRIN (NSAID) / Pain Reliever-Fever Reducer

Dextromethorphan HBr / Cough Suppressant

Phenylephrine Bitartrate / Nasal Decongestant

Nasal Congestion

- Headache & Body Ache
- Cough
- Sore Throat
- Sinus Pressure

### 12 EFFERVESCENT TABLETS

#### **NIGHT**

# ASPIRIN (NSAID) / Pain Reliever-Fever Reducer

Dextromethorphan HBr / Cough Suppressant

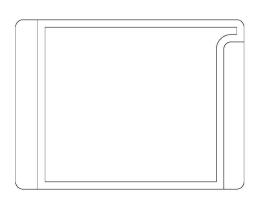
Doxylamine Succinate / Antihistamine

Phenylephrine Bitartrate / Nasal Decongestant

- Nasal Congestion
- Headache & Body Ache
- Cough
- Runny nose
- Sore Throat

#### **8 EFFERVESCENT TABLETS**





Drug Facts (continued)

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# ALKA-SELTZER PLUS COLD DAY AND NIGHT

aspirin, dextromethorphan hydrobromide, phenylephrine bitartrate, doxylamine succinate kit

	Packaging			
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date
:	NDC:0280-1550- 20	1 in 1 CARTON; Type 0: Not a Combination Product	09/14/2018	

Quantity of Parts			
Part #	Package Quantity	Total Product Quantity	
Part 1	6 POUCH	12	
Part 2	4 POUCH	8	

# Part 1 of 2

# **ALKA-SELTZER PLUS COLD DAY**

aspirin, dextromethorphan hydrobromide, phenylephrine bitartrate tablet, effervescent

### **Product Information**

Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
PHENYLEPHRINE BITARTRATE (UNII: 2703Q5ML57) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE BITARTRATE	7.8 mg	
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 mg	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg	

Inactive Ingredients	
Ingredient Name	Strength
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
CALCIUM SILICATE (UNII: S4255P4G5M)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)	
DOCUSATE SODIUM (UNII: F05Q2T2JA0)	
MANNITOL (UNII: 30WL53L36A)	
POVIDONE (UNII: FZ989GH94E)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ASPARTAME (UNII: Z0H242BBR1)	
DIMETHICONE (UNII: 92RU3N3Y1O)	

Product Characteristics			
Color	white	Score	no score
Shape	ROUND	Size	25mm
Flavor	CITRUS	Imprint Code	ASP;DAY
Contains			

l	Packaging				
		ltem Code	Package Description	Marketing Start Date	Marketing End Date
l	1		6 in 1 CARTON		
	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	

# Part 2 of 2

# **ALKA-SELTZER PLUS COLD NIGHT**

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

#### **Product Information**

Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg	
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg	
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	500 mg	
PHENYLEPHRINE BITARTRATE (UNII: 2703Q5ML57) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE BITARTRATE	7.8 mg	

Inactive Ingredients	
Ingredient Name	Strength
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)	

CALCIUM SILICATE (UNII: S4255P4G5M)	
ASPARTAME (UNII: Z0H242BBR1)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
DOCUSATE SODIUM (UNII: F05Q2T2JA0)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
MANNITOL (UNII: 30WL53L36A)	
DIMETHICONE (UNII: 92RU3N3Y1O)	

Product Characteristics			
Color	white	Score	no score
Shape	ROUND	Size	25mm
Flavor	LEMON	Imprint Code	ASP;NT
Contains			

Packaging				
#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1		4 in 1 CARTON		
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	

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.