

**ALKA-SELTZER PLUS MAXIMUM STRENGTH DAY AND NIGHT COLD AND FLU-  
acetaminophen, dextromethorphan hydrobromide, doxylamine succinate,  
phenylephrine hydrochloride  
Bayer HealthCare LLC.**

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**Alka-Seltzer Plus® Maximum Strength Day & Night Cold & Flu Liquid Gels-  
40ct**

**Alka-Seltzer Plus® Maximum Strength Day Cold & Flu Liquid Gels**

**Alka-Seltzer Plus® Maximum Strength Day Cold & Flu Liquid Gels**

***Drug Facts***

***Active ingredients (in each capsule)***

Acetaminophen 325 mg

Dextromethorphan hydrobromide 10 mg

Phenylephrine hydrochloride 5 mg

***Purposes***

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

***Uses***

- temporarily relieves these symptoms due to a cold or flu:
- minor aches and pains · headache · cough
- sore throat · nasal and sinus congestion
- temporarily reduces fever

***Warnings***

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

**Allergy alert:** Acetaminophen may cause severe skin or severe allergic reactions. Symptoms may include:

- skin reddening · blisters · rash · hives
- facial swelling · asthma (wheezing) · shock

If a skin or general allergic reaction occurs, stop use and seek medical help right away.

**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**

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- 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 you have**

- liver disease ● heart disease ● high blood pressure
- 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

**Ask a doctor or pharmacist before use if you are** taking the blood thinning drug warfarin

**When using this product do not exceed recommended dosage**

**Stop use and ask a doctor if**

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

- 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.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

## **Directions**

### ***Directions***

- do not take more than the recommended dose

- adults and children 12 years and over: take 2 capsules with water every 4 hours. Do not exceed 10 capsules in 24 hours or as directed by a doctor.

- children under 12 years: do not use

## **Other information**

### **Other information**

- store at room temperature. Avoid excessive heat above 40°C (104°F).

**Inactive ingredients** FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, shellac, sodium hydroxide, sorbitol sorbitan solution, titanium dioxide

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

## **Alka-Seltzer Plus® Maximum Strength Night Cold & Flu Liquid Gels**

### ***Drug Facts***

#### ***Active ingredients (in each capsule)***

Acetaminophen 325 mg

Dextromethorphan hydrobromide 10 mg

Phenylephrine hydrochloride 5 mg

#### ***Purposes***

Pain reliever/fever reducer

Cough suppressant

## Nasal decongestant

### **Uses**

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- sore throat · nasal and sinus congestion
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- skin reddening · blisters · rash · hives
- facial swelling · asthma (wheezing) · shock

If a skin or general allergic reaction occurs, stop use and seek medical help right away.

**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**

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- 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

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- liver disease ● heart disease ● high blood pressure
- thyroid disease ● diabetes
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- persistent or chronic cough such as occurs with smoking, asthma, or emphysema

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**When using this product do not exceed recommended dosage**

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- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with rash or headache that lasts.

These could be signs of a serious condition.

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**If pregnant or breast-feeding**, ask a health professional before use.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

**Directions**

- do not take more than the recommended dose
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- children under 12 years: do not use

**Other information**

***Other information***

- store at room temperature. Avoid excessive heat above 40°C (104°F).

**Inactive ingredients** FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, shellac, sodium hydroxide, sorbitol sorbitan solution, titanium dioxide

## Questions or comments?

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

## Carton 40 count

Alka-Seltzer PLUS

MAXIMUM STRENGTH

Cold &

Flu

Day NON-DROWSY

ACETAMINOPHEN / Pain Reliever-Fever Reducer

Dextromethorphan HBr / Cough Suppressant

Phenylephrine HCl / Nasal Decongestant

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

24 LIQUID GELS

(Liquid Filled Capsules)

NIGHT

ACETAMINOPHEN / Pain Reliever-Fever Reducer

Dextromethorphan HBr / Cough Suppressant

Doxylamine Succinate / Antihistamine

Phenylephrine HCl / Nasal Decongestant

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

16 LIQUID GELS

(Liquid Filled Capsules)



117/64



OPENING INSTRUCTIONS: "LIFT HERE"

LIFT HERE

**Do not take these products at the same time.**  
 Alka-Seltzer Plus® Maximum Strength Day Cold & Flu Liquid Gels  
 Alka-Seltzer Plus® Maximum Strength Night Cold & Flu Liquid Gels

<p><b>Drug Facts</b></p> <p><b>Active ingredients (in each capsule) Purposes</b></p> <p>Aspirin 325 mg.....Pain reliever/fever reducer</p> <p>Dextromethorphan hydrobromide 10 mg.....Cough suppressant</p> <p>Phenylephrine hydrochloride 5 mg.....Nasal decongestant</p> <p><b>Uses</b></p> <p>temporarily relieves these symptoms due to a cold or flu:        ● minor aches and pains ● headache ● sore throat ● nasal and sinus congestion ● cough</p> <p>temporarily reduces fever</p> <p><b>Warnings</b></p> <p>Liver warnings: This product contains acetaminophen. Severe liver damage may occur if you take more than 4,000 mg of acetaminophen in 24 hours</p> <p>with other drugs containing acetaminophen</p> <p>3 or more alcoholic drinks every day while using the product</p> <p><b>Allergy alert:</b> Acetaminophen may cause severe skin or severe allergic reactions. Symptoms may include:        ● skin redness ● asthma (wheezing) ● rash ● hives ● blisters ● chest ● shock</p> <p>If a skin or general allergic reaction occurs, stop use and seek medical help right away.</p>	<p><b>Drug Facts</b></p> <p><b>Active ingredients (in each capsule) Purposes</b></p> <p>Aspirin 325 mg.....Pain reliever/fever reducer</p> <p>Dextromethorphan hydrobromide 10 mg.....Cough suppressant</p> <p>Phenylephrine hydrochloride 5 mg.....Nasal decongestant</p> <p><b>Uses</b></p> <p>temporarily relieves these symptoms due to a cold or flu:        ● minor aches and pains ● headache ● cough ● sore throat ● nasal and sinus congestion ● temporarily reduces fever</p> <p><b>Warnings</b></p> <p>Liver warnings: This product contains acetaminophen. Severe liver damage may occur if you take more than 4,000 mg of acetaminophen in 24 hours</p> <p>with other drugs containing acetaminophen</p> <p>3 or more alcoholic drinks every day while using the product</p> <p><b>Allergy alert:</b> Acetaminophen may cause severe skin or severe allergic reactions. Symptoms may include:        ● skin redness ● asthma (wheezing) ● rash ● hives ● blisters ● chest ● shock</p> <p>If a skin or general allergic reaction occurs, stop use and seek medical help right away.</p>
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**Day Cold & Flu Liquid Gels**  
**Alka-Seltzer Plus® Maximum Strength**

**Drug Facts (continued)**

**Allergy alert:** Acetaminophen may cause severe skin or severe allergic reactions. Symptoms may include:  
 ● skin redness ● asthma (wheezing) ● rash ● hives ● blisters ● chest ● shock

If a skin or general allergic reaction occurs, stop use and seek medical help right away.

Some throat warnings: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, hoarseness, or vomiting, consult a doctor promptly.

Do not use with any other drug containing acetaminophen (prescription or over-the-counter). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

Inhibitor (MAOI) (certain drugs for depression, painkillers, or other 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 the product.

If you have ever had an allergic reaction to the product or any of its ingredients

**Ask a doctor before use if you have:**  
 ● liver disease ● heart disease ● high blood pressure ● thyroid disease ● diabetes ● glaucoma

**Ask a doctor or pharmacist before use if you are:**  
 ● taking any medicine for high blood pressure ● taking any medicine for heart disease ● taking any medicine for diabetes ● taking any medicine for asthma or emphysema ● taking any medicine for a breathing problem such as emphysema or chronic bronchitis ● taking any medicine for an enlarged prostate gland ● taking any medicine for an enlarged thyroid gland ● taking any medicine for a bleeding problem such as hemophilia ● taking any medicine for a blood thinner such as warfarin

**Day Cold & Flu Liquid Gels**  
**Alka-Seltzer Plus® Maximum Strength**

**Drug Facts (continued)**

**Save throat warnings:** If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, hoarseness, or vomiting, consult a doctor promptly.

Do not use with any other drug containing acetaminophen (prescription or over-the-counter). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

Inhibitor (MAOI) (certain drugs for depression, painkillers, or other 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 the product.

If you have ever had an allergic reaction to the product or any of its ingredients

**Ask a doctor before use if you have:**  
 ● liver disease ● heart disease ● high blood pressure ● thyroid disease ● diabetes ● glaucoma

**Ask a doctor or pharmacist before use if you are:**  
 ● taking any medicine for high blood pressure ● taking any medicine for heart disease ● taking any medicine for diabetes ● taking any medicine for asthma or emphysema ● taking any medicine for a breathing problem such as emphysema or chronic bronchitis ● taking any medicine for an enlarged prostate gland ● taking any medicine for an enlarged thyroid gland ● taking any medicine for a bleeding problem such as hemophilia ● taking any medicine for a blood thinner such as warfarin

INSIDE of EC Flap

Cut Edge

37/8

2



## Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	4 BLISTER PACK	16
Part 2	4 BLISTER PACK	24

## Part 1 of 2

### ALKA-SELTZER PLUS MAXIMUM STRENGTH NIGHT COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride capsule, liquid filled

## Product Information

Route of Administration ORAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
<b>DOXYLAMINE SUCCINATE</b> (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>SHELLAC</b> (UNII: 46N107B71O)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>SORBITAN</b> (UNII: 6O92ICV9RU)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	

## Product Characteristics

Color	green	Score	no score
Shape	OVAL	Size	20mm

<b>Flavor</b>		<b>Imprint Code</b>	AS;NITE
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		4 in 1 CARTON		
1		4 in 1 BLISTER PACK; 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	05/22/2017	

### Part 2 of 2

### ALKA-SELTZER PLUS MAXIMUM STRENGTH DAY COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride capsule, liquid filled

### Product Information

<b>Route of Administration</b>	ORAL
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### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	

<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SHELLAC</b> (UNII: 46N107B71O)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SORBITAN</b> (UNII: 6O92ICV9RU)	

### Product Characteristics

<b>Color</b>	orange	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	AS;DC
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		4 in 1 CARTON		
1		6 in 1 BLISTER PACK; 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	05/22/2017	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	05/22/2017	

### Labeler - Bayer HealthCare LLC. (112117283)

Revised: 12/2025

Bayer HealthCare LLC.