

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

-----  
**Alka-Seltzer Plus® Maximum Strength Day & Night Cold & Flu Liquid Gels-  
20ct**

**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**

- 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**

- 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?**

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

**20 count carton**

Fold Edge

Cut Edge

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

Do not take these products at the same time. DOES NOT CONTAIN ASPIRIN

**Drug Facts**

**Active ingredients (in each capsule)**

Dextromethorphan hydrobromide 10 mg ..... Cough suppressant  
 Doxylamine succinate 5.25 mg ..... Antihistamine  
 Phenylephrine hydrochloride 5 mg ..... Nasal decongestant

**Uses**

temporarily relieves these symptoms due to a cold or flu:  
 • minor aches and pains • headache • cough  
 • nasal congestion • runny nose • sneezing  
 • sore throat

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 redness • hives  
 • skin 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,

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

Do not take these products at the same time. DOES NOT CONTAIN ASPIRIN

**Drug Facts**

**Active ingredients (in each capsule)**

Dextromethorphan hydrobromide 10 mg ..... Cough suppressant  
 Doxylamine succinate 5.25 mg ..... Antihistamine  
 Phenylephrine hydrochloride 5 mg ..... Nasal decongestant

**Uses**

temporarily relieves these symptoms due to a cold or flu:  
 • minor aches and pains • headache • cough  
 • nasal congestion • runny nose • sneezing  
 • sore throat

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 redness • hives  
 • skin 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,

INSIDE of EC Flap

Fold Edge

Cut Edge

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

Do not take these products at the same time. DOES NOT CONTAIN ASPIRIN

**Drug Facts**

**Active ingredients (in each capsule)**

Dextromethorphan hydrobromide 10 mg ..... Cough suppressant  
 Doxylamine succinate 5.25 mg ..... Antihistamine  
 Phenylephrine hydrochloride 5 mg ..... Nasal decongestant

**Uses**

temporarily relieves these symptoms due to a cold or flu:  
 • minor aches and pains • headache • cough  
 • nasal congestion • runny nose • sneezing  
 • sore throat

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 redness • hives  
 • skin 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,

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

Do not take these products at the same time. DOES NOT CONTAIN ASPIRIN

**Drug Facts**

**Active ingredients (in each capsule)**

Dextromethorphan hydrobromide 10 mg ..... Cough suppressant  
 Doxylamine succinate 5.25 mg ..... Antihistamine  
 Phenylephrine hydrochloride 5 mg ..... Nasal decongestant

**Uses**

temporarily relieves these symptoms due to a cold or flu:  
 • minor aches and pains • headache • cough  
 • nasal congestion • runny nose • sneezing  
 • sore throat

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 redness • hives  
 • skin 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,

INSIDE of EC Flap

**LIFT FOR MORE INFORMATION ON DAY & NIGHT**



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

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride kit

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0280-1580
---------------------	----------------	---------------------------	---------------

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0280-1580-20	1 in 1 CARTON; Type 0: Not a Combination Product	05/22/2017	

## Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	2 BLISTER PACK	12
Part 2	2 BLISTER PACK	8

## Part 1 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
--------------------------------	------

## 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:1W5297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

## Inactive Ingredients

Ingredient Name	Strength
<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)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### 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		2 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	

### Part 2 of 2

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

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

### Product Information

<b>Route of Administration</b>	ORAL
--------------------------------	------

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DOXYLAMINE SUCCINATE</b> (UNII: V9B19B5Y12) (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
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 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

<b>Color</b>	green	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	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		2 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	

## 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)

