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

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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:
- $\cdot$  minor aches and pains  $\cdot$  headache  $\cdot$  cough
- $\cdot$  sore throat  $\cdot$  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
- $\cdot$  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:

- $\cdot$  skin reddening  $\cdot$  blisters  $\cdot$  rash  $\cdot$  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

- $\cdot$  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 decongestan

### 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

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- · 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
- $\cdot$  facial swelling  $\cdot$  asthma (wheezing)  $\cdot$  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

Alka-Seltzer PLUS

MAXIMUM STRENGTH

Cold

& Flu

**DAY NON-DROWSY** 

ACETAMINOPHEN/Pain Reliever-Fever Reducer

Dextromethorphan Hydrobromide/Cough Suppressant

Phenylephrine HCl/Nasal Decongestant

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

12 LIQUID GELS (Liquid Filled Capsules)

**NIGHT** 

ACETAMINOPHEN/Pain Reliever-Fever Reducer

Dextromethorphan Hydrobromide/Cough Suppressant

Doxylamine Succinate/Antihistamine

Phenylephrine HCl/Nasal Decongestant

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

8 LIQUID GELS (LiquidFilled Capsules)



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- If you are now taking a prescription monoamine cadase inhibitor (MAOI) (certain drugs for depression, psychiatric, or contains acetaminophen, ask a doctor or pharmacist. with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug

Drug Facts (continued)

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- peraleisent or chronic cough such as occurs with smolding. difficulty in unination due to enlargement of the prost
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  - of its ingredients in children under 12 years of age
- if you are now taking a prescription monoemine oxidese inhibitor (MACA) (caretain drugs for depressarior, psychiatric, or emonitornal conditions, or Parkharon's disease), or for 2 weeks after stopping the MACA drug, if you do not lorow If your prescription drug contains an MACA), sak a doctor or praemastal before staing the product. or thermastal before staing the product. If you have seer had an allergic neartion to this product or any of it by preserved.

Drug Facts (continued)

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

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medical help right away. Soor threat warmings if sore threat is severe, peaslate for more than 20 days, is accompanied or followed by lever, headache, reath, neuses, or vormiting, consult a doctor promptly.

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Drug Facts (continued)

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

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Active ingredients (in each capsule) Purposes

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than 2 days, is accompanied or followed by lever, headache, rash, nauses, or vorniting, consuit a doctor promptly. Do not use to sedete children.

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- With other drugs containing acetaminrophen
   3 or more alcoholic drinks every day while using this product
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- Liver warming. This product contains acetaminopher. Severe **збинилем** 
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Drug Facts (continued)

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

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Active ingredients (in each capsule) Purposes Drug Facts

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

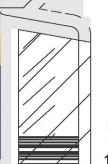
Do not take these products at the same time.

**MAXIMUM STRENGTH** 

Cold & Flu

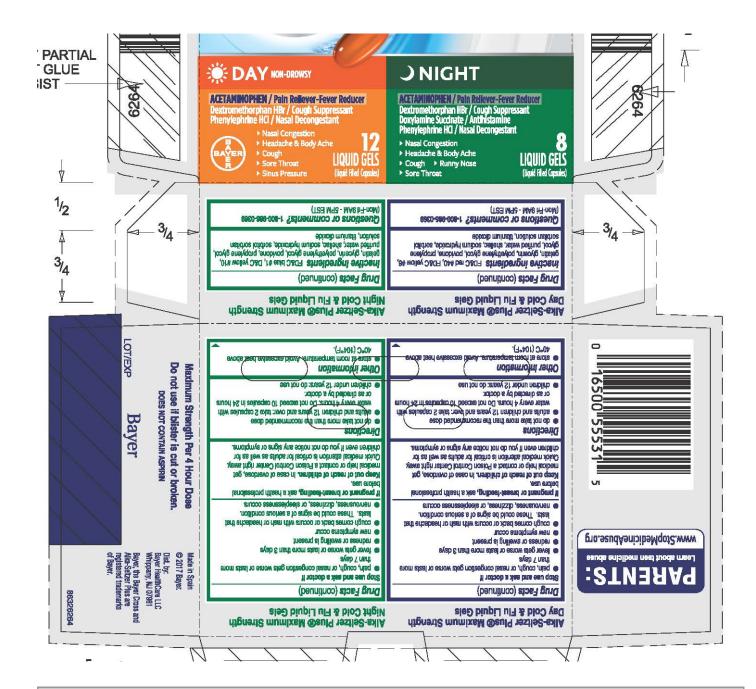
Drug Facts





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

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride kit

# **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:0280-1580

P	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**

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			
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg			
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg			

Inactive Ingredients			
Ingredient Name	Strength		
FD&C RED NO. 40 (UNII: WZB9127XOA)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
GLYCERIN (UNII: PDC6A3C0OX)			
GELATIN (UNII: 2G86QN327L)			
POVIDONE (UNII: FZ 989GH94E)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
SHELLAC (UNII: 46N107B710)			
SODIUM HYDROXIDE (UNII: 55X04QC32I)			
SORBITOL (UNII: 506T60A25R)			
SORBITAN (UNII: 6092ICV9RU)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			

Product Characteristics				
Color	orange	Score	no score	
Shape	OVAL	Size	20mm	
Flavor		Imprint Code	AS;DC	

### Contains

l	Packaging					
	#	ltem Code	Package Description	Marketing Start Date	Marketing End Date	
l	1		2 in 1 CARTON			
	1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product			

Marketing Information					
Marketing Application Number or Monograph Marketing Start Marketing End Category Citation Date 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**

Route of Administration ORAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg		
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg		
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg		

Inactive Ingredients				
Ingredient Name	Strength			
GELATIN (UNII: 2G86QN327L)				
GLYCERIN (UNII: PDC6A3C0OX)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3MJQ0SDW1A)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
POVIDONE (UNII: FZ989GH94E)				
SHELLAC (UNII: 46N107B710)				
SODIUM HYDROXIDE (UNII: 55X04QC32I)				

SORBITAN (UNII: 6092ICV9RU)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SORBITOL (UNII: 506T60A25R)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	

Product Characteristics					
ColorgreenScoreno score					
Shape	OVAL	Size	20mm		
Flavor		Imprint Code	AS;NITE		
Contains	Contains				

Pa	Packaging					
#	ltem 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)

Revised: 12/2023 Bayer HealthCare LLC.