

**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

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Questions or comments?

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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

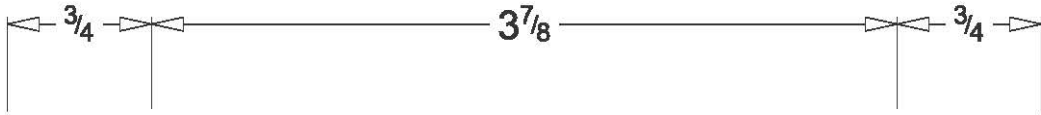
8 LIQUID GELS (Liquid Filled Capsules)



INSIDE of EC Flap

<p>Alka-Seltzer Plus® Maximum Strength Night Cold & Flu Liquid Gels</p> <p>Drug Facts (continued)</p> <ul style="list-style-type: none"> ● 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 ● If you have ever had an allergic reaction to this product or any of its ingredients ● Ask a doctor before use if you have <ul style="list-style-type: none"> ● in children under 12 years of age ● liver disease ● heart disease ● high blood pressure ● thyroid disease ● diabetes ● glaucoma ● cough with excessive phlegm (mucus) ● asthma, or emphysema ● persistent or chronic cough such as occurs with smoking. ● Ask a doctor or pharmacist before use if you are <ul style="list-style-type: none"> ● taking the blood thinning drug warfarin ● taking medicines or treatments 	<p>Alka-Seltzer Plus® Maximum Strength Day Cold & Flu Liquid Gels</p> <p>Drug Facts (continued)</p> <ul style="list-style-type: none"> ● Do not use <ul style="list-style-type: none"> ● 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 ● Ask a doctor before use if you have <ul style="list-style-type: none"> ● in children under 12 years of age ● liver disease ● heart disease ● high blood pressure ● thyroid disease ● diabetes ● glaucoma ● cough with excessive phlegm (mucus) ● asthma, or emphysema ● persistent or chronic cough such as occurs with smoking. ● Ask a doctor or pharmacist before use if you are <ul style="list-style-type: none"> ● taking the blood thinning drug warfarin ● taking medicines or treatments
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Cut Edge

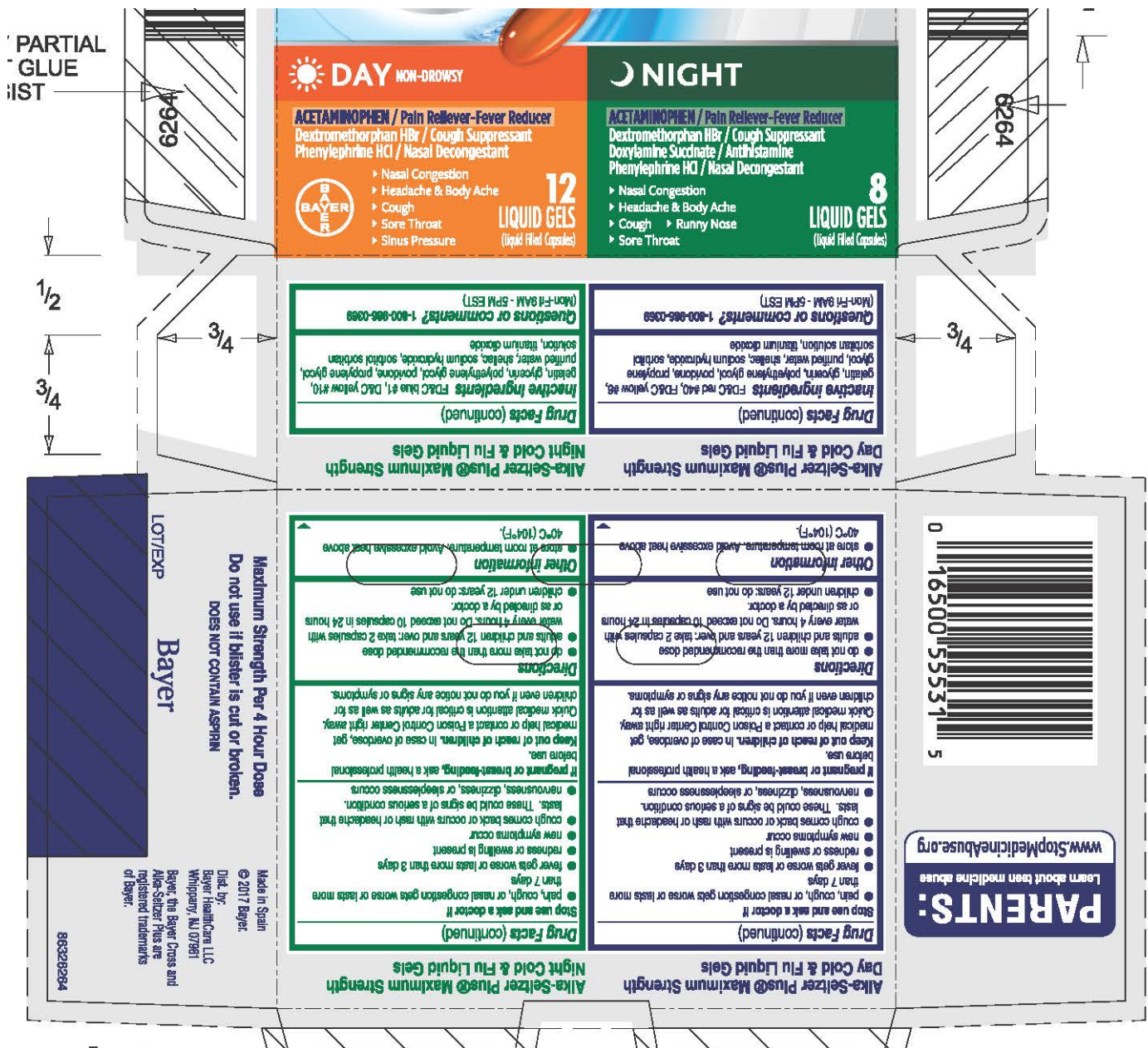


<p>Alka-Seltzer Plus® Maximum Strength Day Cold & Flu Liquid Gels</p> <p>Drug Facts</p> <p>Active ingredients (in each capsule) Purposes</p> <p>Acetaminophen 325 mg Pain reliever/fever reducer</p> <p>Dextromethorphan hydrobromide 10 mg Cough suppressant</p> <p>Phenylephrine hydrochloride 5 mg Nasal decongestant</p>	<p>Alka-Seltzer Plus® Maximum Strength Night Cold & Flu Liquid Gels</p> <p>Drug Facts</p> <p>Active ingredients (in each capsule) Purposes</p> <p>Acetaminophen 325 mg Pain reliever/fever reducer</p> <p>Dextromethorphan hydrobromide 10 mg Cough suppressant</p> <p>Phenylephrine hydrochloride 5 mg Nasal decongestant</p>
<p>Alka-Seltzer Plus® Maximum Strength Day Cold & Flu Liquid Gels</p> <p>Uses</p> <ul style="list-style-type: none"> ● temporarily reduces these symptoms due to a cold or flu: <ul style="list-style-type: none"> ● minor aches and pains ● headache ● cough ● sore throat ● nasal and sinus congestion ● temporarily reduces fever <p>Warnings</p> <p>Liver warnings: This product contains acetaminophen. Severe liver damage may occur if you take</p> <ul style="list-style-type: none"> ● 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 <p>Allergy alert: Acetaminophen may cause severe skin or severe allergic reactions. Symptoms may include:</p> <ul style="list-style-type: none"> ● hives ● rash ● skin redness ● asthma (wheezing) ● shock <p>If a skin or general allergic reaction occurs, stop use and seek medical help right away.</p> <p>Some 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.</p> <p>Do not use to sedate children.</p> <p>Do not use</p> <ul style="list-style-type: none"> ● with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. 	<p>Alka-Seltzer Plus® Maximum Strength Night Cold & Flu Liquid Gels</p> <p>Uses</p> <ul style="list-style-type: none"> ● temporarily reduces these symptoms due to a cold or flu: <ul style="list-style-type: none"> ● minor aches and pains ● headache ● cough ● sore throat ● nasal and sinus congestion ● temporarily reduces fever <p>Warnings</p> <p>Liver warnings: This product contains acetaminophen. Severe liver damage may occur if you take</p> <ul style="list-style-type: none"> ● 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 <p>Allergy alert: Acetaminophen may cause severe skin or severe allergic reactions. Symptoms may include:</p> <ul style="list-style-type: none"> ● hives ● rash ● skin redness ● asthma (wheezing) ● shock <p>If a skin or general allergic reaction occurs, stop use and seek medical help right away.</p> <p>Some 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.</p> <p>Do not use to sedate children.</p> <p>Do not use</p> <ul style="list-style-type: none"> ● with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

49/64

3/4

1/2



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
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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	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	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: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SHELLAC (UNII: 46N107B71O)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

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

Contains**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

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOXYLAMINE SUCCINATE (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1W5297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
POVIDONE (UNII: FZ989GH94E)	
SHELLAC (UNII: 46N107B71O)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

SORBITAN (UNII: 6O92ICV9RU)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SORBITOL (UNII: 506T60A25R)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	

Product Characteristics

Color	green	Score	no score
Shape	OVAL	Size	20mm
Flavor		Imprint Code	AS;NITE
Contains			

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	

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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.