

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

**Alka-Seltzer Plus Maximum Strength Day and Light Cold and Flu Liquid gels
(project Fortify)**

Drug Facts

Alka-Seltzer Plus

Maximum Strength Day & Night Cold & Flu Liquid Gels

Active ingredients (in each capsule) Purposes

Acetaminophen 325 mg.....Pain reliever/fever reducer
Dextromethorphan hydrobromide 10 mg.....Cough suppressant
Phenylephrine hydrochloride 5 mg.....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

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

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

Inactive ingredients FD&C red #40, FD&C yellow #6, gelatin, glycerin, lecithin, light mineral oil, polyethylene glycol, povidone, propylene glycol, purified water, shellac, 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

Active ingredients (in each capsule) Purposes

Acetaminophen 325 mg.....Pain reliever/fever reducer
Dextromethorphan hydrobromide 10 mg.....Cough suppressant
Doxylamine succinate 6.25 mg.....Antihistamine
Phenylephrine hydrochloride 5 mg.....Nasal decongestant

Uses

- temporarily relieves these symptoms due to a cold or flu:
- minor aches and pains · headache
- nasal and sinus congestion · cough · sore throat
- runny nose · sneezing
- 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 to sedate children.

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 ● 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

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

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.

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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 D&C yellow #10, FD&C blue #1, gelatin, glycerin, lecithin, light mineral oil, polyethylene glycol, povidone, propylene glycol, purified water, shellac, sorbitol sorbitan solution, titanium dioxide

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

Alka-Seltzer Plus®

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 Congestion

12 LIQUID GELS

(LIQUID-FILLED CAPSULES)

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	0 BLISTER PACK	1
Part 2	0 BLISTER PACK	1

Part 1 of 2

ALKA-SELTZER PLUS MAXIMUM STRENGTH DAY COLD AND FLU
dextromethorphan hydrobromide, acetaminophen, 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
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SORBITOL (UNII: 506T60A25R)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SHELLAC (UNII: 46N107B71O)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POVIDONE (UNII: FZ989GH94E)	
SORBITAN (UNII: 6O92ICV9RU)	

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		12 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		

Part 2 of 2

ALKA-SELTZER PLUS MAXIMUM STRENGTH NIGHT COLD AND FLU

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

Product Information	
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

Inactive Ingredients	
Ingredient Name	Strength
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
GELATIN (UNII: 2G86QN327L)	
SORBITAN (UNII: 6O92ICV9RU)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SHELLAC (UNII: 46N107B71O)	
SORBITOL (UNII: 506T60A25R)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	

D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)

GLYCERIN (UNII: PDC6A3C0OX)

Product Characteristics

Color	green	Score	no score
Shape	OVAL	Size	21mm
Flavor		Imprint Code	AS;NITE
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 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	10/23/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	10/26/2020	

Labeler - Bayer HealthCare LLC. (112117283)

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Bayer HealthCare LLC.