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

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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 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

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)

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

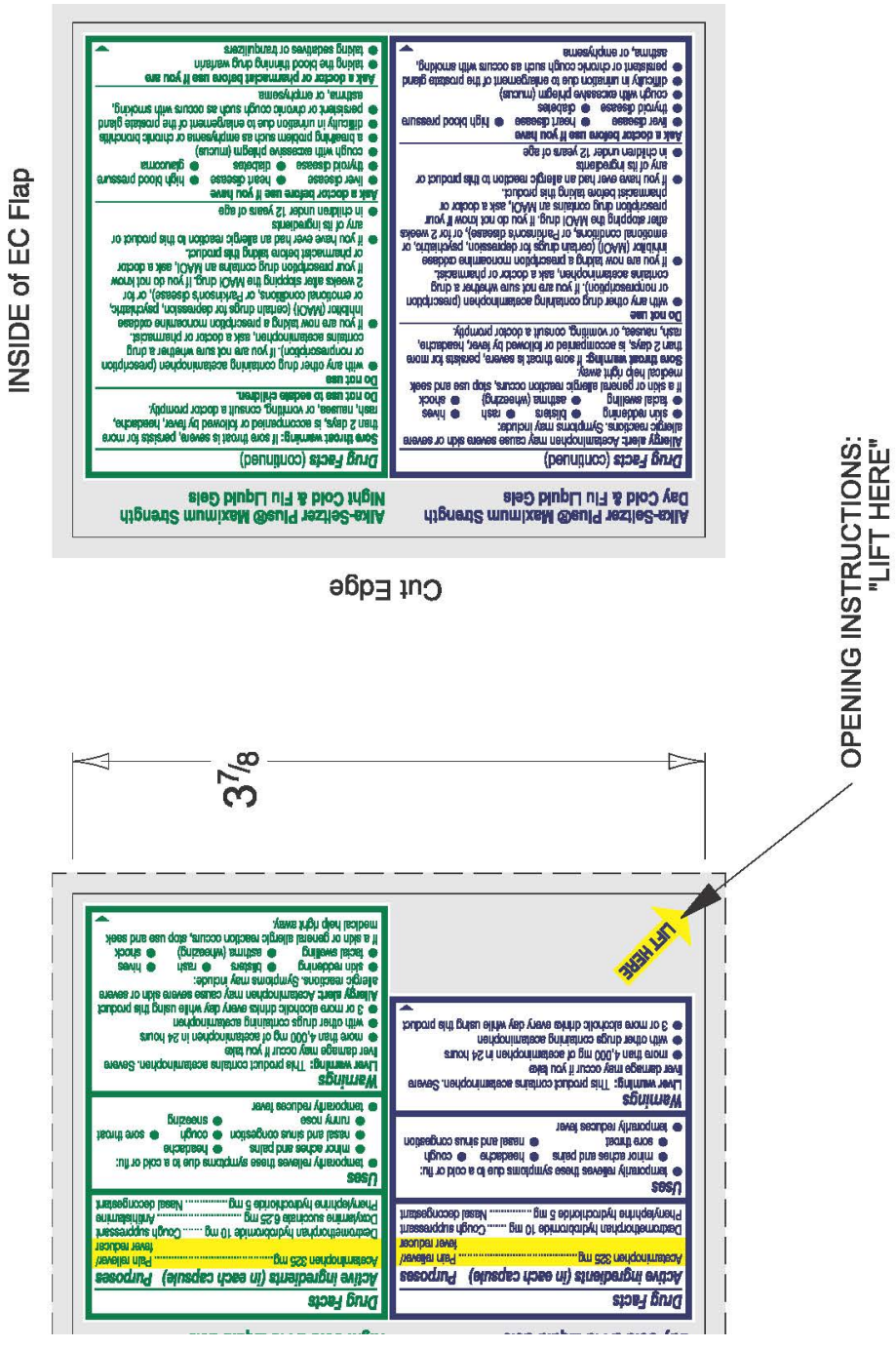
Doxylamine Succinate / Antihistamine

Phenylephrine HCl / Nasal Decongestant

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

16 LIQUID GELS

(Liquid Filled Capsules)



PARENTS:
Learn about teen medicine abuse
www.StopMedicineAbuse.org

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

Drug Facts (continued)

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

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

Drug Facts (continued)

When using this product
- do not exceed recommended dosage
- may cause marked drowsiness
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

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

Maximum Strength Per 4 Hour Dose
Do not use if blister is cut or broken.
DOES NOT CONTAIN ASPIRIN

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Bayer

LOT/EXP

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

Drug Facts (continued)

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 (continued)

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

Inactive ingredients FD&C blue #1, D&C yellow #10, 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)

6272

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)

BAYER

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)

6272

Alka-Seltzer PLUS®
MAXIMUM STRENGTH
Cold & Flu
DAY NON-DROWSY
NIGHT

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

1 17/64
2
3 1/4
1/2
1/2
7 1/4
16

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:0280-1581

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0280-1581-40	1 in 1 CARTON; Type 0: Not a Combination Product	05/22/2017	

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**
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
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: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

Inactive Ingredients	
Ingredient Name	**Strength**
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOLS (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		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 final	part341	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

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**
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
POLYETHYLENE GLYCOLS (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)	

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		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 final	part341	05/22/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/22/2017	

Labeler - Bayer HealthCare LLC. (112117283)

Revised: 6/2018 Bayer HealthCare LLC.