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-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

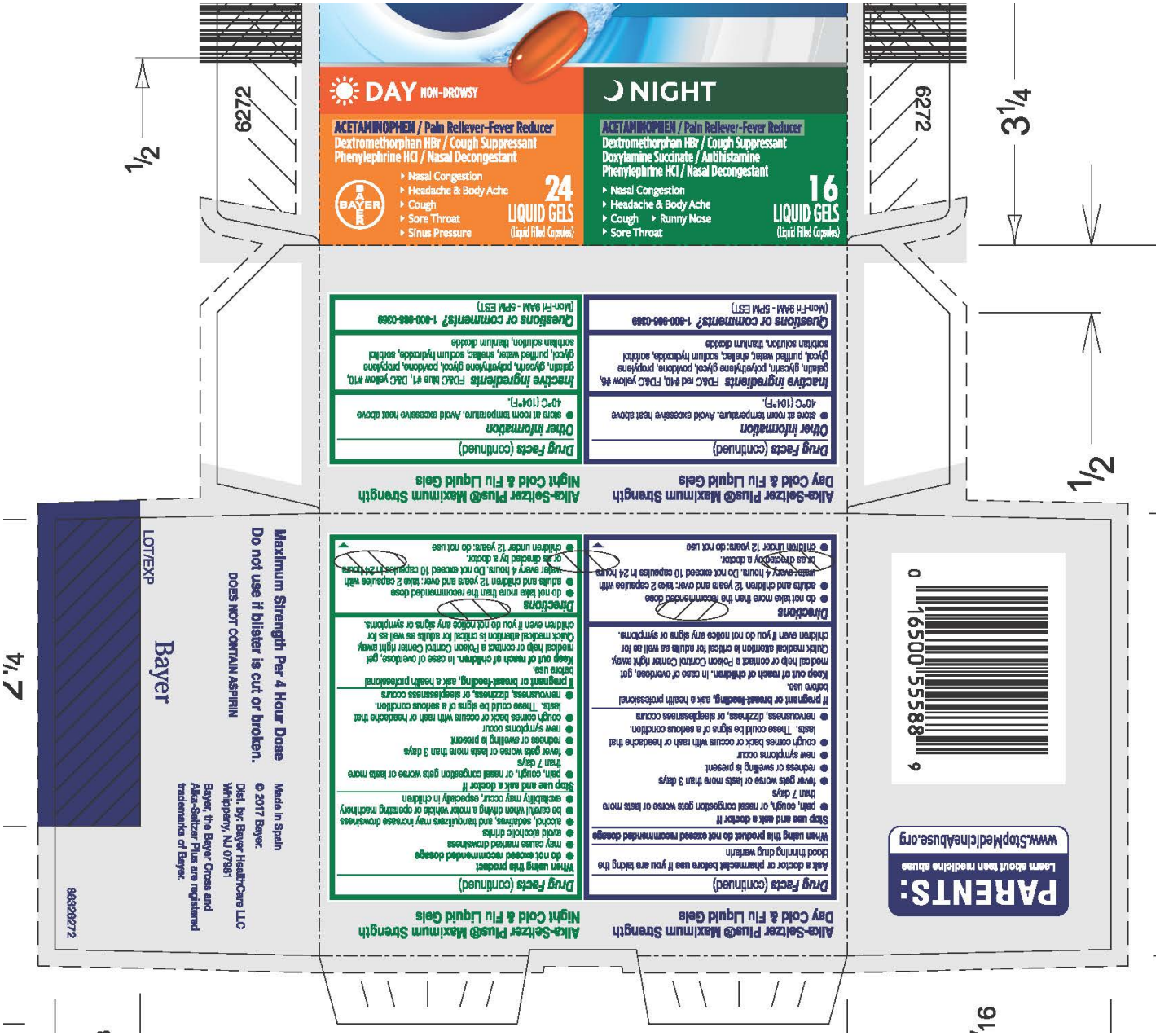
Phenylephrine HCl / Nasal Decongestant

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

16 LIQUID GELS

(Liquid Filled Capsules)

MAXIMUM STRENGTH
Alka-Seltzer PLUS®
Cold & Flu
DAY NON-DROWSY
NIGHT
MAXIMUM STRENGTH
Alka-Seltzer PLUS®
Cold & Flu
Do not take these products at the same time.
Alka-Seltzer Plus® Maximum Strength Day Cold & Flu Liquid Gels
Drug Facts
Active Ingredients (in each capsule) Purpose
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
● nasal and sinus congestion ● runny nose ● sore throat ● 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
Alcohol warning: If you consume 3 or more alcoholic drinks every day, ask a doctor whether you should take acetaminophen or other pain relievers/fevers reducers. Acetaminophen may cause severe liver damage.
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.
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
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 soothe irritation.
Drug Facts (continued)
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)
● 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
Drug Facts (continued)
Alka-Seltzer Plus® Maximum Strength Day Cold & Flu Liquid Gels
Alka-Seltzer Plus® Maximum Strength Night Cold & Flu Liquid Gels
Cut Edge
INSIDE of EC Flap
OPENING INSTRUCTIONS:
"LIFT HERE"
LIFT HERE
3 7/8
1 17/64
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:0280-1581

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 GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
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 Drug	M012	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 GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
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 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.