ALKA-SELTZER PLUS MAXIMUM STRENGTH COUGH, MUCUS AND CONGESTION DAY AND NIGHT- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, guaifenesin, phenylephrine hydrochloride
Bayer HealthCare, LLC.

Alka-Seltzer Plus Maximum Strength Cough, Mucus and Congestion Powermax Day and Night Liquigels UI 1614294 and 1613941

Drug Facts

Do not take these products at the same time.

Alka-Seltzer Plus® Maximum Strength Cough, Mucus & Congestion Day PowerMax® Gels

Active ingredients

Active ingredients (in each capsule) Purposes

Acetaminophen 325 mg……Pain reliever/fever reducer

Dextromethorphan hydrobromide 10 mg……Cough suppressant

Guaifenesin 200 mg……Expectorant

Phenylephrine hydrochloride 5 mg……Nasal decongestant

Uses

Uses

· helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

· temporarily relieves these symptoms due to a cold or flu:

· nasal congestion · sinus congestion and pressure

· minor aches and pains · headache

· cough · sore throat

· temporarily reduces fever

Warnings

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

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

Ask a doctor before use if you have

● liver disease ● heart disease ● high blood pressure

● thyroid disease ● diabetes

● difficulty in urination due to enlargement of the prostate gland

● persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema

● cough with excessive phlegm (mucus)

When using this product

When using this product do not exceed recommended dosage

Ask a doctor or pharmacist before use if you are

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin

Stop use and ask a doctor if

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 fever, rash or headache that lasts.

These could be signs of a serious condition.

· nervousness, dizziness, or sleeplessness occurs

If pregnant or breast-feeding

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children

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

· do not take the Day and Night products at the same time; wait 4 hours

after the last Night dose before starting Day product

· adults and children 12 years and over: take 2 capsules with water

every 4 hours. Do not exceed 6 capsules in 12 hours or as

directed by a doctor.

· children under 12 years: do not use

Other information

Other information

· store at 15°- 25°C (59° - 77°F)

Inactive ingredients

Inactive ingredients FD&C red No. 40, gelatin, glycerin, lecithin, medium chain triglycerides, polyethylene glycol, potassium aluminum silicate, 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)

Alka-Seltzer Plus® Maximum Strength Cough, Mucus & Congestion Night PowerMax® Gels

Drug Facts

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

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

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

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

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

Ask a doctor or pharmacist before use if you are

● taking the blood thinning drug warfarin

● taking sedatives or tranquilizers

When using this product

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

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

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children

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

· do not take the Day and Night products at the same time; wait 4 hours after the last Day dose before starting Night product

· adults and children 12 years and over: take 2 capsules with water every 4 hours. Do not exceed 4 capsules in 12 hours or as directed by a doctor.

· children under 12 years: do not use

Other information

Other information

· store at 15° - 25°C (59° - 77°F)

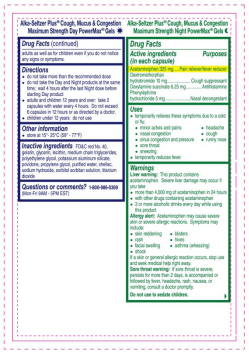
Inactive ingredients

Inactive ingredients D&C yellow No. 10, FD&C blue No. 1, gelatin, glycerin, polyethylene glycol, potassium aluminum silicate, 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)

Package label



ALKA-SELTZER PLUS MAXIMUM STRENGTH COUGH, MUCUS AND CONGESTION DAY AND NIGHT			
acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, guaifenesin, phenylephrine hydrochloride kit			
Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0280-0062

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0280-0062-01	1 in 1 CARTON; Type 0: Not a Combination Product	06/01/2020	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	3 BLISTER PACK	6
Part 2	1 BLISTER PACK	2

Part 1 of 2

ALKA-SELTZER PLUS MAXIMUM STRENGTH COUGH, MUCUS AND CONGESTION DAY POWERMAX

acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride

capsule, liquid filled

Product Information

Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
GELATIN (UNII: 2G86QN327L)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
POVIDONE (UNII: FZ989GH94E)	
WATER (UNII: 059QF0KO0R)	
SHELLAC (UNII: 46N107B71O)	
SORBITAN (UNII: 6O92ICV9RU)	

SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
POTASSIUM ALUMINUM DISILICATE (UNII: SRB14JRX6C)	

Product Characteristics			
Color	red	**Score**	no score
Shape	OVAL (ELLIPTICAL)	**Size**	20mm
Flavor		**Imprint Code**	ASP;S
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		2 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	06/01/2020	

Part 2 of 2

ALKA-SELTZER PLUS MAXIMUM STRENGTH COUGH, MUCUS AND CONGESTION NIGHT POWERMAX

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
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
GELATIN (UNII: 2G86QN327L)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
SORBITOL (UNII: 506T60A25R)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
POVIDONE (UNII: FZ989GH94E)	
SHELLAC (UNII: 46N107B71O)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SORBITAN (UNII: 6O92ICV9RU)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POTASSIUM ALUMINUM DISILICATE (UNII: SRB14JRX6C)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	green	**Score**	no score
Shape	OVAL (ELLIPTICAL)	**Size**	17mm
Flavor		**Imprint Code**	ASP;N
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		2 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	06/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	06/01/2020	

Labeler - Bayer HealthCare, LLC. (112117283)