

**ALKA-SELTZER PLUS MAXIMUM STRENGTH COUGH, MUCUS AND CONGESTION
POWERMAX- acetaminophen, dextromethorphan hydrobromide, guaifenesin,
phenylephrine hydrochloride capsule, liquid filled
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 Cough, Mucus & Congestion Liquigels UI
1614294**

Drug Facts

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

Purpose

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)

Ask a doctor or pharmacist

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

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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
- 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 15° - 25°C (59° - 77°F)

Inactive ingredients

Inactive ingredients FD&C red #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)

Package label carton 24

NEW

Alka-Seltzer

PLUS®

MAXIMUM

STRENGTH

Cough,

Mucus &

Congestion

POWERMAX® GELS

CONCENTRATED FORMULA

ACETAMINOPHEN / Pain Reliever-Fever Reducer

Dextromethorphan HBr / Cough Suppressant

Guaifenesin / Expectorant

Phenylephrine HCl / Nasal Decongestant

For *Fast Relief* of:

- Nasal/Chest Congestion
- Headache, Body Ache Sore Throat, Fever
- Cough
- Mucus

24 LIQUID GELS (Liquid Filled Capsules)



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

acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0280-0061
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
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
SORBITAN (UNII: 6O92ICV9RU)	

WATER (UNII: 059QF0KO0R)
GELATIN (UNII: 2G86QN327L)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
POVIDONE (UNII: FZ989GH94E)
SORBITOL (UNII: 506T60A25R)
SHELLAC (UNII: 46N107B71O)
POTASSIUM ALUMINUM DISILICATE (UNII: SRB14JRX6C)
FD&C RED NO. 40 (UNII: WZB9127XOA)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SODIUM HYDROXIDE (UNII: 55X04QC32I)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ05DW1A)

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	NDC:0280-0061-01	2 in 1 CARTON	06/01/2020	
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0280-0061-02	2 in 1 CARTON	06/01/2020	
2		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 final	part341	06/01/2020	

Labeler - Bayer HealthCare LLC. (112117283)