ALKA-SELTZER PLUS MAXIMUM STRENGTH COUGH, MUCUS AND CONGESTION POWERMAX- acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride capsule, liquid filled
Bayer HealthCare LLC.

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 commens

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 Thoat, 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: 3WQ0SDW1A)	

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 Drug	M012	06/01/2020	

Labeler - Bayer HealthCare LLC. (112117283)

Revised: 12/2023 Bayer HealthCare LLC.