ALKA-SELTZER PLUS MAXIMUM STRENGTH SEVERE SINUS, ALLERGY AND COUGH- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride capsule, liquid filled
Bayer HealthCare LLC.

Alka-Seltzer Plus® Maximum Strength Severe Sinus, Allergy & Cough Liquid Gels

Drug Facts

Active ingredients (in each capsule)

Acetaminophen 325 mg

Dextromethorphan hydrobromide 10 mg

Doxylamine succinate 6.25 mg

Phenylephrine hydrochloride 5 mg

Purposes

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Nasal decongestan

Uses

Uses

· temporarily relieves these symptoms due to hay fever or other upper

respiratory allergies:

· runny nose · sneezing

· itching of the nose or throat · itchy, watery eyes

· temporarily relieves these symptoms due to a cold:

· nasal congestion · sinus congestion and pressure

· headache · minor aches and pains · cough

· 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.

Do not use to sedate children.

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 ● 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

● taking the blood thinning drug warfarin

● taking sedatives or tranquilizers

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

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 40ºC

(104ºF)

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

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Dextromethorphan hydrobromide 10 mg	Cough suppressant
Doxylamine succinate 6.25 mg	Antihistamine
Phenylephrine hydrochloride 5 mg	Nasal decongestant

Uses

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
  - runny nose
  - sneezing
  - itching of the nose or throat
  - itchy, watery eyes
- temporarily relieves these symptoms due to a cold:
  - nasal congestion
  - sinus congestion and pressure
  - headache
  - minor aches and pains
  - cough
- temporarily reduces fever

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Drug Facts (continued)

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Ask a doctor before use if you have

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ALKA-SELTZER PLUS MAXIMUM STRENGTH SEVERE SINUS, ALLERGY AND COUGH

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0280-1620
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
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

Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
WATER (UNII: 059QF0KO0R)	
SHELLAC (UNII: 46N107B71O)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Product Characteristics

Color	green	**Score**	no score
Shape	OVAL	**Size**	20mm
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0280-1620-20	2 in 1 CARTON	06/26/2017	
1		10 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	06/26/2017	

Labeler - Bayer HealthCare LLC. (112117283)

Revised: 12/2023 Bayer HealthCare LLC.