

**ALKA-SELTZER PLUS MAXIMUM STRENGTH NIGHT COLD AND FLU POWERMAX GELS- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride capsule, liquid filled
Bayer HealthCare LLC.**

Alka-Seltzer Plus® Maximum Strength Night Cold & Flu PowerMax™ 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 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

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4000 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

- 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

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 temperatures above 25°C (77°F).

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)



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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0280-1640
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
DOXYLAMINE SUCCINATE (UNII: V08109EY12) (DOXYLAMINE SUCCINATE - UNII:V08109EY12)	DOXYLAMINE SUCCINATE	10 mg

DOXYLAMINE SUCCINATE (UNII: V9B19B5Y1Z) (DOXYLAMINE - UNII:95QB77JKPL)

DOXYLAMINE SUCCINATE

6.25 mg

Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
GELATIN (UNII: 2G86QN327L)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	
SHELLAC (UNII: 46N107B71O)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SORBITAN (UNII: 6O92ICV9RU)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics

Color	green	Score	no score
Shape	OVAL	Size	16mm
Flavor		Imprint Code	ASP;N
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0280-1640-16	2 in 1 CARTON	07/02/2018	
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0280-1640-24	3 in 1 CARTON	07/02/2018	
2		8 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	07/02/2018	

Labeler - Bayer HealthCare LLC. (112117283)