

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

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**Alka-Seltzer Plus® Maximum Strength Day Cold & Flu PowerMax™ Gels**

***Drug Facts***

***Active ingredients (in each capsule)***

Acetaminophen 325 mg

Dextromethorphan hydrobromide 10 mg

Phenylephrine hydrochloride 5 mg

***Purposes***

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

**Uses**

***Uses***

- temporarily relieves these symptoms due to a cold or flu:
- minor aches and pains · headache · cough
- sore throat · nasal and sinus congestion
- 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.

**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**

- 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
- cough with excessive phlegm (mucus)
- 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

**When using this product do not exceed recommended dosage**

**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***

- 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***

- store at room temperature. Avoid temperatures above 25°C (77°F).

***Inactive ingredients*** FD&C yellow #6, ferric oxide, 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)

### **16 count carton**

Alka Seltzer Plus®

Cold & Flu

POWERMAX GELS™

CONCENTRATED FORMULA

DAY NON DROWSY

### **ACETAMINOPHEN / Pain Reliever-Fever Reducer**

Dextromethorphan Hydrobromide / Cough Suppressant

Phenylephrine HCl / Nasal Decongestant

- Cough
- Nasal Congestion
- Headache & Body Ache
- Sore Throat
- Sinus Pressure

16 LIQUID GELS (Liquid Filled Capsules)



# ALKA-SELTZER PLUS MAXIMUM STRENGTH DAY COLD AND FLU POWERMAX GELS

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride capsule, liquid filled

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0280-1630
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
<b>ACETAMINOPHEN</b> (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDWL1A)	
<b>SHELLAC</b> (UNII: 46N107B710)	
<b>SORBITAN</b> (UNII: 6O92ICV9RU)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>GELATIN</b> (UNII: 2G86QN327L)	

**FERROSFERRIC OXIDE** (UNII: XM0M87F357)

**WATER** (UNII: 059QF0KO0R)

**GLYCERIN** (UNII: PDC6A3C0OX)

**SODIUM HYDROXIDE** (UNII: 55X04QC32I)

**SORBITOL** (UNII: 506T60A25R)

**PROPYLENE GLYCOL** (UNII: 6DC9Q167V3)

**FD&C YELLOW NO. 6** (UNII: H77VEI93A8)

**POVIDONE** (UNII: FZ989GH94E)

### Product Characteristics

<b>Color</b>	orange	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	16mm
<b>Flavor</b>		<b>Imprint Code</b>	ASP;DC
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0280-1630-16	2 in 1 CARTON	07/02/2018	
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0280-1630-24	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)

Revised: 12/2023

Bayer HealthCare LLC.