**ALKA-SELTZER PLUS COLD DAY AND NIGHT POWERMAX GELS- acetaminophen, dextromethorphan hydrobromide, phenylephrine bitartrate, doxylamine succinate**
**Bayer HealthCare LLC.**

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**Alka-Seltzer Plus Max Strength Sinus congestion & Pain Day & Night PowerMax gels**

Alka-Seltzer Plus® Maximum Strength Sinus Congestion & Pain Day PowerMax® Gels

***Drug Facts***

***Active ingredients (in each tablet)***

Acetaminophen 325 mg……Pain reliever/fever reducer

Dextromethorphan hydrobromide 10 mg……Cough suppressant

Phenylephrine hydrochloride 5 mg……Nasal decongestant

***Uses***

temporarily relieves these symptoms due to a cold or flu:

· minor aches and pains · headache · cough

· sore throat · nasal congestion

· sinus congestion and pressure

· 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**

liver disease ● heart disease ● high blood pressure

● thyroid disease ● diabetes

● cough that occurs 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**

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.

**Directions**

***Directions***

do not take more than the recommended dose

· do not take the Day and Night products at the same time; wait 4 hours after the last Night dose before starting Day product.

· adults and children 12 years and over: take 2 capsules with water every 4 hours. Do not exceed 6 capsules in 12 hours or as directed by a doctor.

· children under 12 years: do not use

Other information

● store at room temperature. Avoid temperatures above 40ºC (104ºF).

***SPL***

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? 1-800-986-0369 (Mon-Fri 9AM -5PM EST)

**Package Display Label**


Alka-Seltzer

PLUS®

# ALKA-SELTZER PLUS COLD DAY AND NIGHT POWERMAX GELS

acetaminophen, dextromethorphan hydrobromide, phenylephrine bitartrate, doxylamine succinate kit

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:0280-0099 |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:0280-0099-01 | 1 in 1 CARTON; Type 0: Not a Combination Product | 09/14/2018 | |

## Quantity of Parts

| Part # | Package Quantity | Total Product Quantity |
|---|---|---|
| **Part 1** | 2 CAPSULE | 12 |
| **Part 2** | 1 CAPSULE | 4 |

## Part 1 of 2

### ALKA-SELTZER PLUS MAXIMUM STRENGTH SINUS, CONGESTION AND PAIN POWER MAX GELS

acetaminophen, dextromethorphan hydrobromide , phenylephrine hydrochloride capsule, liquid filled

## Product Information

| | |
|---|---|
| **Item Code (Source)** | NDC:0280-0095 |
| **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: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 10 mg |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **POTASSIUM ALUMINUM DISILICATE** (UNII: SRB14JRX6C) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **SORBITAN** (UNII: 6O92ICV9RU) | |
| **SODIUM HYDROXIDE** (UNII: 55X04QC32I) | |
| **GELATIN** (UNII: 2G86QN327L) | |
| **POVIDONE** (UNII: FZ989GH94E) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **SORBITOL** (UNII: 506T60A25R) | |
| **SHELLAC** (UNII: 46N107B71O) | |
| **FD&C YELLOW NO. 6** (UNII: H77VEI93A8) | |

### Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | orange | **Score** | no score |
| **Shape** | OVAL | **Size** | 17mm |
| **Flavor** | | **Imprint Code** | ASP;CC |
| **Contains** | | | |

### Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | | 2 in 1 BLISTER PACK | | |
| **1** | | 8 in 1 CAPSULE; 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 | 07/01/2021 | |

## Part 2 of 2

## ALKA SELTZER PLUS MAXIMUM STRENGTH SINUS, ALLERGY AND COUGH POWER MAX GELS

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

### Product Information

| | |
|---|---|
| **Item Code (Source)** | NDC:0280-0097 |
| **Route of Administration** | ORAL |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **DEXTROMETHORPHAN HYDROBROMIDE** (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 10 mg |
| **DOXYLAMINE SUCCINATE** (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL) | DOXYLAMINE SUCCINATE | 6.25 mg |
| **ACETAMINOPHEN** (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 325 mg |
| **PHENYLEPHRINE HYDROCHLORIDE** (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 5 mg |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **SHELLAC** (UNII: 46N107B71O) | |
| **D&C YELLOW NO. 10** (UNII: 35SW5USQ3G) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **POTASSIUM ALUMINUM DISILICATE** (UNII: SRB14JRX6C) | |
| **SORBITAN** (UNII: 6O92ICV9RU) | |
| **SODIUM BENZOATE** (UNII: OJ245FE5EU) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | green | **Score** | no score |
| **Shape** | OVAL (Elliptical) | **Size** | 17mm |
| **Flavor** | | **Imprint Code** | ASP;N |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | | 2 in 1 BLISTER PACK | | |
| **1** | | 4 in 1 CAPSULE; 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 | 09/14/2018 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC Monograph Drug | M012 | 07/01/2018 | |

**Labeler -** Bayer HealthCare LLC. (112117283)

Revised: 12/2023 Bayer HealthCare LLC.