**ALKA-SELTZER PLUS SEVERE COLD AND FLU POWERFAST FIZZ-**
**chlorpheniramine maleate, acetaminophen, phenylephrine hydrochloride, dextromethorphan hydrobromide tablet, effervescent**
**R J General Corporation**

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**Alka-Seltzer Plus ® Cold Medicine Sparkling Original**

***Drug Facts***

| ***Active ingredients (in each tablet)*** | ***Purposes*** |
|---|---|
| Acetaminophen 250 mg | Pain reliever/fever reducer |
| Chlorpheniramine maleate 2 mg | Antihistamine |
| Dextromethorphan hydrobromide 10 mg | Cough suppressant |
| Phenylephrine hydrochloride 5 mg | Nasal decongestant |

**Uses**

- temporarily relieves these symptoms due to a cold or flu:
- 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 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
- a sodium restricted diet

**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***

- do not take more than the recommended dose
- adults and children 12 years and over: take 2 tablets fully dissolved in 4 oz of water every 4 hours. Do not exceed 8 tablets in 24 hours or as directed by a doctor.
- children under 12 years: do not use

***Other information***

- **each tablet contains:** potassium 80 mg; sodium 356 mg
- store at room temperature. Avoid excessive heat.

**Inactive ingredients**

anhydrous citric acid, calcium silicate, dimethicone, FDC red #40, FDC yellow #6, flavors, magnesium stearate, maltodextrin, mannitol, potassium bicarbonate, povioone, sodium bicarbonate, sucralose.

***Questions or comments?***
**1-800-986-0369** (Mon-Fri 9AM – 5PM EST)

**PRINCIPAL DISPLAY PANEL - 60 Tablet Carton**

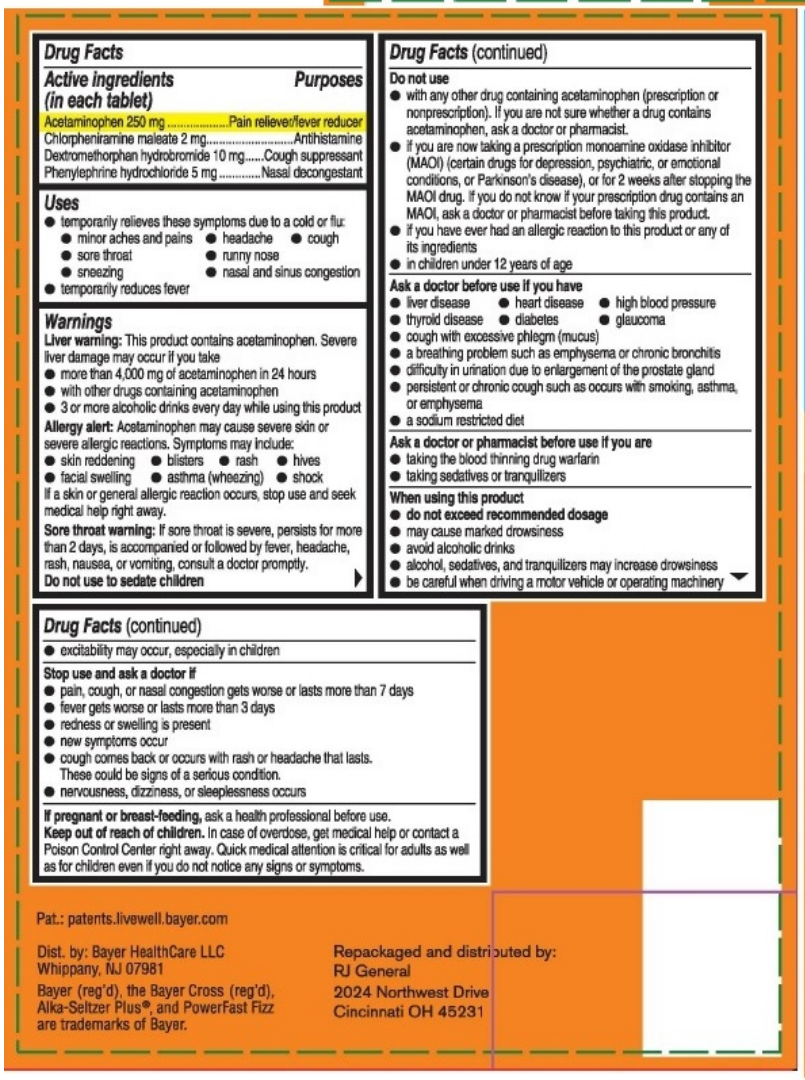
***Alka-***
***Seltzer***
***PLUS*** ®
*Acetaminophen / Pain reliever/fever reducer*
*Chlorpheniramine maleate / Antihistamine*
*Dextromethorphan hydrobromide / Cough suppressant*
*Phenylephrine hydrochloride / Nasal decongestant*

***COLD***
***FORMULA***

***SPARKLING***
***ORIGINAL***

***Nasal Congestion • Runny Nose***
***Headache & Body Ache***
***Sore Throat • Sinus Pressure***


Alka-Seltzer PLUS®
SEVERE
Cold & Flu
CITRUS
BAYER
POWERFAST FIZZ™
Alka-Seltzer PLUS®
SEVERE
Cold & Flu
CITRUS
BAYER
POWERFAST FIZZ™
30 EFFERVESCENT TABLETS
Alka-Seltzer PLUS®
SEVERE
Cold & Flu
CITRUS



**ALKA-SELTZER PLUS SEVERE COLD AND FLU POWERFAST FIZZ**

chlorpheniramine maleate, acetaminophen, phenylephrine hydrochloride, dextromethorphan hydrobromide tablet, effervescent

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:70264-016(NDC:0280-0022) |
| **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 | 250 mg |
| **DEXTROMETHORPHAN HYDROBROMIDE** (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 10 mg |
| **CHLORPHENIRAMINE MALEATE** (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U) | CHLORPHENIRAMINE MALEATE | 2 mg |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **FD&C YELLOW NO. 6** (UNII: H77VEI93A8) | |
| **DIMETHICONE** (UNII: 92RU3N3Y1O) | |
| **CALCIUM SILICATE** (UNII: S4255P4G5M) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **MALTODEXTRIN** (UNII: 7CVR7L4A2D) | |
| **MANNITOL** (UNII: 3OWL53L36A) | |
| **POVIDONE** (UNII: FZ989GH94E) | |
| **FD&C RED NO. 40** (UNII: WZB9127XOA) | |
| **ANHYDROUS CITRIC ACID** (UNII: XF417D3PSL) | |
| **SUCRALOSE** (UNII: 96K6UQ3ZD4) | |
| **POTASSIUM BICARBONATE** (UNII: HM5Z15LEBN) | |
| **SODIUM BICARBONATE** (UNII: 8MDF5V39QO) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | white (Speckled) | **Score** | no score |
| **Shape** | ROUND | **Size** | 25mm |
| **Flavor** | | **Imprint Code** | ASP;FLU |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:70264-016-01 | 30 in 1 CARTON | 03/16/2023 | |
| **1** | | 2 in 1 POUCH; 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 | 03/16/2023 | |

## Labeler - R J General Corporation (122542830)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| R J General Corporation | | 122542830 | repack(70264-016) |

Revised: 10/2024 R J General Corporation