

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

Alka-Seltzer Plus[®] Cold Medicine Sparkling Original

Drug Facts

<i>Active ingredients (in each tablet)</i>	<i>Purposes</i>
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, povidone, 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

BAYER

CITRUS

POWERFAST Fizz™

The top section of the packaging features a blue background with a large circular logo for 'Alka-Seltzer PLUS' in white and yellow. To the right, a dark blue banner contains the text 'SEVERE' and 'Cold & Flu'. Below this, a light blue area shows the Bayer logo and the word 'CITRUS'. At the bottom of this section, a gold banner displays 'POWERFAST Fizz™'. The design is accented with images of white effervescent tablets, a slice of grapefruit, and a slice of lemon.



Alka-Seltzer PLUS

SEVERE


Cold & Flu

BAYER

CITRUS

POWERFAST Fizz™

This middle section is identical in design to the top section, featuring the 'Alka-Seltzer PLUS' logo, 'SEVERE Cold & Flu' text, Bayer logo, 'CITRUS' label, and 'POWERFAST Fizz™' branding on a blue background with white and yellow accents.



30 EFFERVESCENT TABLETS

The bottom section of the packaging is a solid orange color. It features a dashed line border and a small semi-circular cutout at the top center. The text '30 EFFERVESCENT TABLETS' is centered in white.



Alka-Seltzer PLUS

SEVERE

Cold & Flu

BAYER

CITRUS

POWERFAST Fizz™

This bottom section is identical in design to the top and middle sections, featuring the 'Alka-Seltzer PLUS' logo, 'SEVERE Cold & Flu' text, Bayer logo, 'CITRUS' label, and 'POWERFAST Fizz™' branding on a blue background with white and yellow accents.

POWERFAST FIZZ

ACETAMINOPHEN / Pain Reliever-Fever Reducer
 Chlorpheniramine Maleate / Antihistamine
 Dextromethorphan HBr / Cough Suppressant
 Phenylephrine Hydrochloride / Nasal Decongestant

- Fever & Body Ache
- Cough
- Nasal Congestion
- Runny Nose
- Sore Throat

PARENTS:
 Learn about teen medicine abuse
www.StopMedicineAbuse.org



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Do not use if pouch is torn or broken
 Made in Mexico

<p>Drug Facts</p> <p>Active ingredients (in each tablet)</p> <p>Acetaminophen 250 mgPain reliever/fever reducer Chlorpheniramine maleate 2 mg.....Antihistamine Dextromethorphan hydrobromide 10 mg.....Cough suppressant Phenylephrine hydrochloride 5 mg.....Nasal decongestant</p> <p>Purposes</p> <p>temporarily relieves these symptoms due to a cold or flu: ● minor aches and pains ● headache ● cough ● sore throat ● runny nose ● sneezing ● nasal and sinus congestion ● temporarily reduces fever</p> <p>Warnings</p> <p>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</p> <p>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.</p> <p>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</p>	<p>Drug Facts (continued)</p> <p>Do not use</p> <ul style="list-style-type: none"> ● 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 <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> ● 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 <p>Ask a doctor or pharmacist before use if you are</p> <ul style="list-style-type: none"> ● taking the blood thinning drug warfarin ● taking sedatives or tranquilizers <p>When using this product</p> <ul style="list-style-type: none"> ● 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
<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> ● excitability may occur, especially in children <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> ● 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 <p>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.</p>	
<p>Pat.: patents.livewell.bayer.com</p> <p>Dist. by: Bayer HealthCare LLC Whippany, NJ 07981</p> <p>Bayer (reg'd), the Bayer Cross (reg'd), Alka-Seltzer Plus®, and PowerFast Fizz are trademarks of Bayer.</p> <p>Repackaged and distributed by: RJ General 2024 Northwest Drive Cincinnati OH 45231</p>	



SEVERE

Cold & Flu

CITRUS

POWERFAST FIZZ™

- Fever & Body Ache
- Cough
- Nasal Congestion
- Runny Nose
- Sore Throat

ACETAMINOPHEN / Pain Reliever-Fever Reducer
 Chlorpheniramine Maleate / Antihistamine
 Dextromethorphan HBr / Cough Suppressant
 Phenylephrine Hydrochloride / Nasal Decongestant

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Other information

- each tablet contains: potassium 80 mg; sodium 356 mg
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Inactive ingredients anhydrous citric acid, calcium silicate, dimethicone, FD&C red #40, FD&C yellow #6, flavors, magnesium stearate, maltodextrin, mannitol, potassium bicarbonate, povidone, sodium bicarbonate, sucralose

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

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:1W5297W6MV)	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: 70097M6I3O)	
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: 10/2023

R J General Corporation