ALKA SELTZER PLUS SEVERE COLD AND FLU POWERFAST FIZZchlorpheniramine maleate, acetaminophen, phenylephrine hydrochloride, dextromethorphan hydrobromide tablet, effervescent tablet, effervescent Select Corporation

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Alka Seltzer Plus® Severe Cold and Flu 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:
 - minor aches and pains
 - headache
 - cough
 - sore throat
 - runny nose
 - sneezing
 - 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 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 a 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, 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)

PRINCIPAL DISPLAY PANEL - 2 Tablet Pouch Blister Pack

Alka-Seltzer PLUS®

ACETAMINOPHEN / Pain Reliever-Fever Reducer Chlorpheniramine Maleate / Antihistamine Dextromethorphan HBr / Cough Suppressant

Phenylephrine Hydrochloride / Nasal Decongestant

SEVERE Cold

& Flu

CITRUS

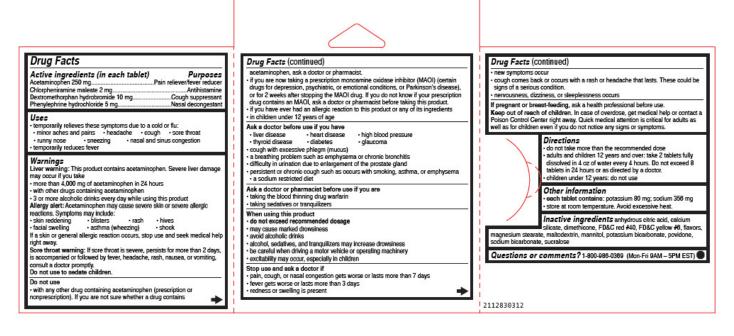
- Fever & Body Ache Cough Nasal Congestion Runny Nose Sore Throat

BAYER

POWER FAST FiZZ™

2 **EFFERVESCENT** Tablets Single-Pack





ALKA SELTZER PLUS SEVERE COLD AND FLU POWERFAST FIZZ

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

Active Ingredient/Active Moiety

| Product Information | | | |
|----------------------------|----------------|--------------------|------------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:52904-830(NDC:0280-0022) |
| Route of Administration | ORAL | | |
| | | | |
| | | | |

| Ingredient Name | Basis of Strength | Strength |
|--|----------------------------------|----------|
| Acetaminophen (UNII: 36209ITL9D) (Acetaminophen - UNII:36209ITL9D) | Acetaminophen | 250 mg |
| Dextromethorphan hydrobromide (UNII: 9D2RTI9KYH) (Dextromethorphan - UNII:7355X3ROTS) | Dextromethorphan hydrobromide | 10 mg |
| Phenylephrine hydrochloride (UNII: 04JA59TNSJ) (Phenylephrine - UNII:1WS297W6MV) | Phenylephrine hydrochloride | 5 mg |
| Chlorpheniramine maleate (UNII: V1Q0O9OJ9Z) (Chlorpheniramine - UNII: 3U6IO1965U) | Chlorpheniramine maleate | 2 mg |

| Inactive Ingredients | | |
|--|----------|--|
| Ingredient Name | Strength | |
| acesulfame potassium (UNII: 230V73Q5G9) | | |
| anhydrous citric acid (UNII: XF417D3PSL) | | |
| FD&C red no. 40 (UNII: WZB9127XOA) | | |
| magnesium stearate (UNII: 70097M6I30) | | |
| maltodextrin (UNII: 7CVR7L4A2D) | | |
| mannitol (UNII: 3OWL53L36A) | | |
| saccharin sodium (UNII: SB8ZUX40TY) | | |
| sodium bicarbonate (UNII: 8MDF5V39QO) | | |

| Product Characteristics | | | |
|-------------------------|------------------|--------------|----------|
| Color | WHITE (Speckled) | Score | no score |
| Shape | ROUND | Size | 25mm |
| Flavor | CITRUS | Imprint Code | ASP;FLU |
| Contains | | | |

| P | Packaging | | | | |
|---|----------------------|---|-------------------------|-----------------------|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| 1 | NDC:52904-830- 04 | 1 in 1 BLISTER PACK | 07/03/2017 | | |
| 1 | | 2 in 1 POUCH; Type 0: Not a Combination Product | | | |
| 2 | NDC:52904-830- 05 | 2 in 1 BLISTER PACK | 07/03/2017 | | |
| 2 | | 2 in 1 POUCH; Type 0: Not a Combination Product | | | |
| 3 | NDC:52904-830- 20 | 20 in 1 CARTON | 07/03/2017 | | |
| 3 | | 2 in 1 POUCH; Type 0: Not a Combination Product | | | |
| 4 | NDC:52904-830- 25 | 25 in 1 CARTON | 07/03/2017 | | |
| 4 | | 2 in 1 POUCH; Type 0: Not a Combination Product | | | |
| 5 | NDC:52904-830- 30 | 30 in 1 CARTON | 07/03/2017 | | |
| 5 | | 2 in 1 POUCH; Type 0: Not a Combination Product | | | |
| | | | | | |

| Marketing Information | | | | |
|---|---|---|--|--|
| Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | | |
| part341 | 07/03/2017 | | | |
| | Application Number or Monograph Citation | Application Number or Monograph Marketing Start Citation Date | | |

Labeler - Select Corporation (053805599)

Revised: 5/2022 Select Corporation