ALKA-SELTZER PLUS SEVERE COLD NIGHT POWERFAST FIZZ- aspirin, chlorpheniramine maleate, dextromethorphan hydrobromide, phenylephrine bitartrate tablet, effervescent
Bayer HealthCare LLC.

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-Selzer Plus Severe Cold PowerFast Fizz Night effervescent tablets UI 1614459

Drug Facts

Active ingredients (in each tablet) Purposes

Aspirin 325 mg (NSAID)*.....Pain reliever/fever reducer

Chlorpheniramine maleate 2 mg.....Antihistamine

Dextromethorphan hydrobromide 10 mg.....Cough suppressant

Phenylephrine bitartrate 7.8 mg.....Nasal decongestant

*nonsteroidal anti-inflammatory drug

Uses

- temporarily relieves these symptoms due to a cold:
  - minor aches and pains
  - headache
  - runny nose
  - sinus congestion and pressure
  - cough
  - sneezing
  - sore throat
  - nasal congestion
- temporarily reduces fever

Warnings

Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.
Allergy alert: Aspirin may cause a severe allergic reaction which may include:

- hives
- facial swelling
- asthma (wheezing)
- shock

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you

- are age 60 or older

- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

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
- if you are allergic to aspirin or any other pain reliever/fever reducer
- 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
- stomach bleeding warning applies to you
  - you have a history of stomach problems, such as heartburn
  - you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
  - you are taking a diuretic
  - you have
    - asthma
    - diabetes
    - thyroid disease
    - glaucoma
    - cough that occurs 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 a prescription drug for
  - gout
  - diabetes
  - arthritis
- 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

- an allergic reaction occurs. Seek medical help right away.
- you experience any of the following signs of stomach bleeding
  - feel faint
  - vomit blood
  - have bloody or black stools
  - have stomach pain that does not get better
- 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
- ringing in the ears or a loss of hearing occurs
- 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.

It is especially important not to use aspirin at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

● 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 of age: 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, flavors, mannitol, potassium bicarbonate, povidone, sodium bicarbonate, sucralose

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

Carton 24 count

RESTRICTED

Alka-Seltzer Plus®

SEVERE

Cold

LEMON

POWERFAST FIZZ™ SEE NEW DOSING DIRECTIONS

NIGHT

Aspirin **(NSAID)**/Pain Reliever-Fever Reducer

Chlorpheniramine Maleate / Antihistmine

Dextromethorphan HBr / Cough Suppressant

Phenylephrine Bitartrate / Nasal Decongestant

- Nasal Congestion
- Headache + Body Ache
- Cough
- Runny Nose
- Sore Throat

24 EFFERVESCENT TABLETS

ALKA-SELTZER PLUS SEVERE COLD NIGHT POWERFAST FIZZ

aspirin, chlorpheniramine maleate, dextromethorphan hydrobromide, phenylephrine bitartrate
tablet, effervescent

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0280-0121
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 mg
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
PHENYLEPHRINE BITARTRATE (UNII: 27O3Q5ML57) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE BITARTRATE	7.8 mg

Inactive Ingredients	
Ingredient Name	**Strength**
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CALCIUM SILICATE (UNII: S4255P4G5M)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
MANNITOL (UNII: 3OWL53L36A)	
POTASSIUM BICARBONATE (UNII: HM5Z15LEBN)	
POVIDONE (UNII: FZ989GH94E)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics			
Color	white	**Score**	no score
Shape	ROUND	**Size**	25mm
Flavor	LEMON	**Imprint Code**	ASP;NT
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0280-0121-01	12 in 1 CARTON	05/24/2023	
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:0280-0121-	10 in 1 CARTON	05/24/2023	

2	02	10 in 1 CARTON	05/24/2023	
2		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 final	part341	05/24/2023	

Labeler - Bayer HealthCare LLC. (112117283)

Revised: 8/2023 Bayer HealthCare LLC.