ALKA-SELTZER PLUS MAXIMUM STRENGTH SINUS CONGESTION AND PAIN POWERFAST FIZZ- chlorpheniramine maleate, dextromethorphan hydrobromide, acetaminophen, phenylephrine hydrochloride 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.

ASP Maximum Strength Sinus Congestion and Pain PowerFast Fizz UI1614734

Drug Facts

Active ingredients (in each tablet) Purposes

Acetaminophen 325 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 congestion · sinus

temporarily reduces fever

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 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 10 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, 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®

MAXIMUM STRENGTH

Sinus

Congestion

& Pain

PowerFast Fizz™

Berry

New!

Actaminophen/Pain Reliever-Fever Reducer

Chlorpheniramine Maleate/Antihistamine

Dextromethorphan HBr/Cough Supressant

Phenylephrine Hydrochloride/Nasal Decongestant

- Sinus Congestion & Pressure
- Nasal Congestion
- Headache, Body Ache, Sore Throat
- Runny Nose, Sneezing
- Cough

24 EFFERVESCENT TABLETS

ALKA-SELTZER PLUS MAXIMUM STRENGTH SINUS CONGESTION AND PAIN POWERFAST FIZZ

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

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0280-0055
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CALCIUM SILICATE (UNII: S4255P4G5M)	
MANNITOL (UNII: 3OWL53L36A)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POTASSIUM BICARBONATE (UNII: HM5Z15LEBN)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
DIMETHICONE (UNII: 92RU3N3Y1O)	

Product Characteristics			
Color	white	**Score**	no score
Shape	ROUND	**Size**	25mm

Flavor	BERRY (Raspberry and Mixed Berry)	**Imprint Code**	SINUS
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0280-0055-01	10 in 1 CARTON	06/15/2021	
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:0280-0055-02	12 in 1 CARTON	03/08/2023	
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	06/15/2021	

Labeler - Bayer HealthCare LLC. (112117283)

Revised: 8/2023 Bayer HealthCare LLC.