ALKA-SELTZER PLUS SEVERE COLD AND FLU POWERFAST FIZZ-
chlorpheniramine maleate, acetaminophen, phenylephrine hydrochloride, dextromethorphan hydrobromide tablet, effervescent
Navajo Manufacturing Company Inc.

Alka-Seltzer Plus Severe Cold & Flu PowerFast Fizz

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 childre

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

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

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

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Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67751-217(NDC:0280-0022)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 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:67751-217-01	1 in 1 CARTON	06/01/2022	
1		1 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:67751-217-02	1 in 1 CARTON	06/01/2022	
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 Drug	M012	06/01/2022	

Labeler - Navajo Manufacturing Company Inc. (091917799)

Establishment

Name	Address	ID/FEI	Business Operations
Navajo Manufacturing Company Inc.		136941411	relabel(67751-217) , repack(67751-217)

Revised: 10/2024 Navajo Manufacturing Company Inc.