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

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 & 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 final	part341	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: 3/2023 Navajo Manufacturing Company Inc.