

ALKA-SELTZER PLUS COLD AND FLU, CVP- chlorpheniramine maleate, acetaminophen, phenylephrine hydrochloride, dextromethorphan hydrobromide tablet tablet, effervescent

ALKA-SELTZER PLUS COLD AND FLU, BASIX- chlorpheniramine maleate, acetaminophen, phenylephrine hydrochloride, dextromethorphan hydrobromide tablet tablet, effervescent

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Lil' Drug Store Products, 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

Drug Facts

Active ingredients

Active ingredients (in each tablet)

Acetaminophen 250 mg

Chlorpheniramine maleate 2 mg

Dextromethorphan hydrobromide 10 mg

Phenylephrine hydrochloride 5 mg

Purposes

Purposes

Pain reliever/fever reducer

Antihistamine

Cough suppressant

Nasal decongestant

Uses

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

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

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

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

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

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 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

Other information

- **each tablet contains:** potassium 80 mg; sodium 356 mg
- store at room temperature. Avoid excessive heat.

Inactive ingredients

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)

**DO NOT USE IF INNER POUCH OR CARTON IS OPEN OR DAMAGED!
PACKAGE NOT CHILD RESISTANT!**

PDP/Package - Lil Drug Store

Alka-

Seltzer

Plus ®

CITRUS

FLAVOR

SEVERE Cold & Flu

POWERFAST FIZZ™

ACETAMINOPHEN/Pain Reliever-Fever Reducer

Chlorpheniramine Maleate/Antihistamine

Dextromethorphan HBr/Cough Suppressant

Phenylephrine Hydrochloride/Nasal Decongestant

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

4

Effervescent Tablets

[Lil' Drug Store logo]



PDP/Package - BASIX

Alka-Seltzer Plus®

CITRUS FLAVOR

SEVERE Cold & Flu

POWERFAST FIZZ™

ACETAMINOPHEN/Pain Reliever-Fever Reducer

Chlorpheniramine Maleate/Antihistamine

Dextromethorphan HBr/Cough Suppressant

Phenylephrine Hydrochloride/Nasal Decongestant

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

4

Effervescent Tablets

[TRAVEL

BASIX logo]



PDP/Package - Alka-Seltzer Plus Cold & Flu, CVP

Alka-Seltzer Plus®

CITRUS FLAVOR

SEVERE Cold & Flu

POWERFAST FIZZ™

ACETAMINOPHEN/Pain Reliever-Fever Reducer

Chlorpheniramine Maleate/Antihistamine

Dextromethorphan HBr/Cough Suppressant

Phenylephrine Hydrochloride/Nasal Decongestant

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



Alka-Seltzer Plus Cold & Flu, 30ct Unit Dose Box

Alka-Seltzer PLUS®

CITRUS FLAVOR

SEVERE COLD & FLU POWERFAST FIZZ™

ACETAMINOPHEN/Pain Reliever-Fever Reducer

Chlorpheniramine Maleate/Antihistamine

Dextromethorphan HBr/Cough Suppressant

Phenylephrine Hydrochloride/Nasal Decongestant

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

2 EFFERVESCENT TABLETS PER POUCH



ALKA-SELTZER PLUS COLD AND FLU, CVP

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66715-6531
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	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
POTASSIUM BICARBONATE (UNII: HM5Z15LEBN)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

DIMETHICONE (UNII: 92RU3N3Y1O)	
MAGNESIUM STEARATE (UNII: 70097M6I3O)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
CALCIUM SILICATE (UNII: S4255P4G5M)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MANNITOL (UNII: 3OWL53L36A)	

Product Characteristics

Color	white (speckled)	Score	no score
Shape	ROUND	Size	25mm
Flavor	CITRUS	Imprint Code	ASP;FLU
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66715-6531-2	2 in 1 CARTON	08/01/2022	
1		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	04/25/2022	

ALKA-SELTZER PLUS COLD AND FLU, BASIX

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66715-7831
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	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
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Inactive Ingredients

Ingredient Name	Strength
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POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
CALCIUM SILICATE (UNII: S4255P4G5M)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
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Product Characteristics

Color	white (speckled)	Score	no score
Shape	ROUND	Size	25mm
Flavor	CITRUS	Imprint Code	ASP;FLU
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66715-7831-2	2 in 1 CARTON	11/30/2022	
1		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	11/30/2022	

ALKA-SELTZER PLUS COLD AND FLU

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66715-9831
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Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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Product Characteristics

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Shape	ROUND	Size	25mm
Flavor	CITRUS	Imprint Code	ASP;FLU
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66715-9831-2	2 in 1 CARTON	04/25/2022	
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:66715-9831-8	25 in 1 BOX, UNIT-DOSE; Type 0: Not a Combination Product	04/27/2022	
3	NDC:66715-9831-9	30 in 1 BOX, UNIT-DOSE; Type 0: Not a Combination Product	05/17/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	04/25/2022	

Labeler - Lil' Drug Store Products, Inc. (093103646)

Revised: 4/2023

Lil' Drug Store Products, Inc.