ALKA-SELTZER PLUS NIGHT SEVERE COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, and phenylephrine hydrochloride powder, for solution
Bayer HealthCare LLC.

Alka-Seltzer Plus ® Night Severe Cold + Flu

Drug Facts

Active ingredients (in each packet)	***Purposes***
Acetaminophen 650 mg	Pain reliever/fever reducer
Dextromethorphan hydrobromide 20 mg	Cough suppressant
Doxylamine succinate 12.5 mg	Antihistamine
Phenylephrine hydrochloride 10 mg	Nasal decongestant

Uses

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

Warnings

Liver warning

This product contains acetaminophen. Severe liver damage may occur if you take

- more than 5 packets in 24 hours, which is the maximum daily amount for this product
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

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

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
- take every 4 hours; do not exceed 5 packets in 24 hours or as directed by a doctor
- adults and children 12 years and over: dissolve contents of one packet in 8 oz. hot water; sip while hot. Consume entire drink within 10-15 minutes.
- children under 12 years: do not use

Other information

- **each packet contains:** potassium 5 mg and sodium 5 mg
- store at room temperature

Inactive ingredients

acesulfame potassium, anhydrous citric acid, compressible sugar, D&C yellow #10, dental-type silica, FD&C red #40, flavors, pregelatinized starch, sodium citrate, sucralose, tartaric acid, tribasic calcium phosphate

Questions or comments?

1-800-986-0369
(Mon-Fri 9AM - 5PM EST)

Dist. by: Bayer HealthCare LLC
Whippany, NJ 07981

PRINCIPAL DISPLAY PANEL - 6 Packet Carton

Alka-Seltzer PLUS ®

Severe

Cold & Flu

Honey Lemon Zest

Fast Relief Mix-In Packets

Night

Acetaminophen */ Pain reliever-fever reducer*

Doxylamine succinate / Antihistamine

Phenylephrine HCl / Nasal decongestant

Dextromethorphan HBr / Cough suppressant

- ***Nasal Congestion***
- ***Headache***

- ***Sore Throat***
- ***Body Ache***
- ***Cough***
- ***Runny Nose***
- ***Fever***

6 PACKETS

ALKA-SELTZER PLUS NIGHT SEVERE COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, and phenylephrine hydrochloride powder, for solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0280-0922
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TARTARIC ACID (UNII: W4888I119H)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	
STARCH, CORN (UNII: O8232NY3SJ)	
SUCROSE (UNII: C151H8M554)	
MENTHOL (UNII: L7T10EIP3A)	
LEMON (UNII: 24RS0A988O)	
HONEY (UNII: Y9H1V576FH)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	yellow	**Score**	
Shape		**Size**	
Flavor	LEMON, HONEY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0280-0922-06	6 in 1 CARTON	04/17/2014	04/30/2020
1		1 in 1 PACKET; 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	04/17/2014	

Labeler - Bayer HealthCare LLC. (112117283)

Establishment

Name	Address	ID/FEI	Business Operations
Contract Pharmacal Corp.		968335112	manufacture(0280-0922)

Revised: 1/2024 Bayer HealthCare LLC.