SEVERE COLD PLUS FLU DAYTIME NIGHTTIME- acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride, and doxylamine succinate
CVS Pharmacy,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.

CVS Health™ Severe Cold plus Flu Daytime Nighttime

SEVERE COLD + FLU DAYTIME

Drug Facts

Active ingredients (in each packet)	*Purposes*
Acetaminophen 500 mg	Pain reliever/fever reducer
Dextromethorphan hydrobromide 20 mg	Cough suppressant
Guaifenesin 400 mg	Expectorant
Phenylephrine hydrochloride 10 mg	Nasal decongestant

Uses

- temporarily relieves these symptoms due to a cold or flu:
  - minor aches and pains
  - headache
  - sore throat
  - cough
  - nasal congestion
  - sinus congestion and pressure
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus
- temporarily reduces fever

Warnings

Liver warning

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

- more than 6 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

ALLERGY ALERT

Acetaminophen may cause severe skin or severe allergic reactions. Symptoms may include:

- Skin reddening

- Blisters
- Rash
- Hives
- facial swelling
- asthma(wheezing)
- shock

  Is 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

- 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
- difficulty in urination due to enlargement of the prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema
- cough with excessive phlegm (mucus)

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin

When using this product do not exceed recommended dosage

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 at 1-800-222-1222. 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 6 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 6 mg**
- store at room temperature

Inactive ingredients

anhydrous citric acid, flavors, maltodextrin, potassium citrate, silica, sucralose, sucrose, yellow#6

Questions or comments?

1-866-467-2748

SEVERE COLD + FLU NIGHTTIME

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

ALLERGY ALERT

Acetaminophen may cause severe skin reactions. Symptoms may include:

- Skin reddening
- Blisters
- Rash
- Hives
- facial swelling
- asthma (wheezing)
- shock

Is 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

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 at 1-800-222-1222. 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 6 mg**
- store at room temperature

Inactive ingredients

anhydrous citric acid, flavors, maltodextrin, potassium citrate, silica, sucralose, sucrose, yellow#6

Questions or comments?

1-866-467-2748

PRINCIPAL DISPLAY PANEL-

Compare to Alka-Seltzer PLUS® Severe Cold +Flu Day and Night Active Ingredients*

DAYTIME

SEVERE COLD & FLU

Acetaminophen / Pain reliever-fever reducer

Dextromethorphan HBr / Cough suppressant

Guaifenesin / Expectorant
Phenylephrine HCl / Nasal decongestant

Relieves:
• Nasal Congestion • Headache
• Sore Throat • Body Ache • Cough
• Mucus • Chest Congestion • Fever

Honey Lemon Flavor

Naturally and Artificially Flavored

NIGHTTIME

Severe Cold & Flu

Acetaminophen / Pain reliever-fever reducer

Dextromethorphan HBr / Cough suppressant
Doxylamine succinate / Antihistamine
Phenylephrine HCl / Nasal decongestant

Relieves:

• Nasal Congestion • Headache
• Sore Throat • Body Ache
• Cough • Runny Nose • Fever

Honey Lemon Flavor

Naturally and Artificially Flavored

TAMPER EVIDENT: DO NOT USE IF INDIVIDUAL POUCH IS TORN OR OPEN

DO NOT TAKE THESE PRODUCTS AT THE SAME TIME

6 DAY PACKETS + 6 NIGHT PACKETS
12 TOTAL

Distributed by: CVS Pharmacy, Inc.

One CVS Drive Woonsocket, RI 02895

CVS.com® 1-800-SHOP CVS

Money Back Guarantee

***These products is not manufactured or distributed by Bayer Healthcare, LLC, distributor of Alka-Seltzer plus® Severe Cold +Flu Day and Night.**

SEVERE COLD PLUS FLU DAYTIME NIGHTTIME

acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride, and doxylamine succinate kit

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69842-546

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-546-12	1 in 1 CARTON; Type 0: Not a Combination Product	07/14/2017	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 CARTON	6
Part 2	1 CARTON	6

Part 1 of 2

SEVERE COLD PLUS FLU DAYTIME

acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride powder, for solution

Product Information

Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
POTASSIUM CITRATE (UNII: EE90ONI6FF)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SUCROSE (UNII: C151H8M554)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		6 in 1 CARTON; 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	07/14/2017	

Part 2 of 2

SEVERE COLD PLUS FLU NIGHTTIME

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

Product Information

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
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
POTASSIUM CITRATE (UNII: EE90ONI6FF)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SUCROSE (UNII: C151H8M554)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		6 in 1 CARTON; 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	07/14/2017	

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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/14/2017	

Labeler - CVS Pharmacy,Inc. (062312574)