

**DAY COLD AND FLU PLUS AND NIGHTTIME COLD AND FLU PLUS- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride
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.

DAY Cold & Flu Plus and NIGHTTIME Cold & Flu Plus

COLD & FLU FORMULA DAY NON-DROWSY

Active ingredients (in each softgel)

Acetaminophen 325 mg
Dextromethorphan hydrobromide 10 mg
Phenylephrine hydrochloride 5 mg

COLD & FLU FORMULA NIGHT

Active ingredients (in each softgel)

Acetaminophen 325 mg
Dextromethorphan hydrobromide 10 mg
Doxylamine succinate 6.25 mg
Phenylephrine hydrochloride 5 mg

Purposes

DAY COLD & FLU FORMULA

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

Purposes

NIGHT COLD & FLU FORMULA

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Nasal decongestant

Uses

DAY COLD & FLU FORMULA

- temporarily relieves these symptoms due to a cold or flu:
 - minor aches and pains
 - headache
 - cough
 - sore throat
 - nasal and sinus congestion

- temporarily reduces fever

Uses

NIGHT COLD & FLU FORMULA

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

DAY COLD & FLU FORMULA

Warnings

Liver warning

These products contain acetaminophen. Severe liver damage may occur if you take

- more than 10 softgels 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.

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

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
- cough with excessive phlegm (mucus)

- 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.

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. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

NIGHTTIME COLD & FLU FORMULA

Warnings

Liver warning

These products contain acetaminophen. Severe liver damage may occur if you take

- more than 10 softgels 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.

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

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.

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If pregnant or breast-feeding, ask a health professional before use.

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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.

DAY COLD & FLU FORMULA

Directions

- do not take more than the recommended dose
- adults and children 12 years and over: take 2 softgels with water every 4 hours. Do not exceed 10 softgels in 24 hours or as directed by a doctor.
- children under 12 years: do not use

NIGHTTIME COLD & FLU FORMULA

Directions

- do not take more than the recommended dose
- adults and children 12 years and over: take 2 softgels with water every 4 hours. Do not exceed 10 softgels in 24 hours or as directed by a doctor.
- children under 12 years: do not use

DAY COLD & FLU FORMULA

Other information

- store at room temperature. Avoid excessive heat.

NIGHTTIME COLD & FLU FORMULA

Other information

- store at room temperature. Avoid excessive heat.

DAY COLD & FLU FORMULA

Inactive ingredients

FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol special, and white edible ink

NIGHTTIME COLD & FLU FORMULA

Inactive ingredients

D&C yellow #10, FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol special, and white edible ink

DAY COLD & FLU FORMULA

Questions or comments?

Call toll free: 1-855-215-8180

NIGHTTIME COLD & FLU FORMULA

Questions or comments?

Call toll free: 1-855-215-8180

Principal Display Panel - Carton Label

CVS NON-DROWSY DAY Cold & Flu Plus and NIGHTTIME Cold & Flu Plus 20ct

NDC 69842-069-08

*Compare to the active ingredients in Alka-Seltzer PLUS[®] Day and Night Cold and Flu Formula

DO NOT TAKE THESE PRODUCTS AT THE SAME TIME

COLD & FLU FORMULA - DAY

Drug Facts

Warnings

Directions

Other information

Keep out of reach of children.

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CVS Health.

NON-DROWSY DAY Cold & Flu Plus

NIGHTTIME Cold & Flu Plus

Sinus Pain

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CVS Health.

NON-DROWSY DAY Cold & Flu Plus

ACETAMINOPHEN - Pain reliever; Fever reducer
DEXTROMETHORPHAN HBr - Cough suppressant
PHENYLEPHRINE HCl - Nasal decongestant

Relieves:
 Nasal congestion; Cough;
 Headache & body aches;
 Sore throat; Runny nose

Actual Size
12 SOFTGELS

NON-DROWSY DAY Cold & Flu Plus

ACETAMINOPHEN - Pain reliever; Fever reducer
DEXTROMETHORPHAN HBr - Cough suppressant
DOXYLAMINE SUCCINATE - Antihistamine
PHENYLEPHRINE HCl - Nasal decongestant

Relieves:
 Nasal congestion; Cough;
 Headache & body aches;
 Sore throat; Runny nose

Actual Size
8 SOFTGELS

CVS Quality

MADE IN CHINA

CVS PHARMACY, INC.

1-800-245-6249

CVS PHARMACY, INC.

1-800-245-6249

KEEP THIS AREA

DO NOT TAKE THESE PRODUCTS AT THE SAME TIME

COLD & FLU FORMULA - DAY

Drug Facts

Warnings

Directions

Other information

Keep out of reach of children.

© 2014 CVS Health

KEEP THIS AREA

DO NOT TAKE THESE PRODUCTS AT THE SAME TIME

COLD & FLU FORMULA - DAY NON-DROWSY

Drug Facts

Warnings

Directions

Other information

Keep out of reach of children.

© 2014 CVS Health

CVS Health.

NON-DROWSY DAY Cold & Flu Plus

NIGHTTIME Cold & Flu Plus

Sinus Pain

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NON-DROWSY DAY Cold & Flu Plus

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COLD & FLU FORMULA - DAY NON-DROWSY

Drug Facts

Warnings

Directions

Other information

Keep out of reach of children.

© 2014 CVS Health

THIS PRODUCT IS PACKAGED IN A CHILD-RESISTANT AND TAMPER-EVIDENT CONTAINER. THE ONLY WAY TO OPEN IS BY BREAKING THE SEAL.

PARENTS:
 www.cvshealth.com

48770242



CVS PHARMACY, INC. 1-800-245-6249

KEEP THIS AREA



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COLD & FLU FORMULA • DAY NON-DROWSY**Drug Facts** (continued)

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.

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

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
- cough with excessive phlegm (mucus)
- 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.

When using this product do not exceed recommended dosage

COLD & FLU FORMULA • NIGHT**Drug Facts** (continued)**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

DAY COLD AND FLU PLUS AND NIGHTTIME COLD AND FLU PLUS

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-069
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-069-08	1 in 1 CARTON; Type 0: Not a Combination Product	12/13/2016	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BLISTER PACK	12
Part 2	1 BLISTER PACK	8

DAY COLD AND FLU PLUS

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride capsule, liquid filled

Product Information

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	5 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	orange (clear)	Score	no score
Shape	capsule (oblong)	Size	20mm
Flavor		Imprint Code	PC9
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		
1		12 in 1 BLISTER PACK; 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	12/13/2016	

Part 2 of 2

NIGHTTIME COLD AND FLU PLUS

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride capsule, liquid filled

Product Information

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	5 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	green (clear)	Score	no score
Shape	capsule (oblong)	Size	20mm
Flavor		Imprint Code	PC22
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		
1		8 in 1 BLISTER PACK; 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	12/13/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	12/13/2016	

Labeler - CVS PHARMACY, INC. (062312574)

Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceuticals (Wuhan) Co., Ltd		421293287	manufacture(69842-069) , analysis(69842-069)

Revised: 11/2019

CVS PHARMACY, INC.