

**CVS DAYTIME COLD AND FLU RELIEF AND NIGHTTIME COLD AND FLU RELIEF-
acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, guaifenesin,
phenylephrine hydrochloride
PuraCap Pharmaceutical LLC**

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.

Daytime COLD & FLU RELIEF and Nighttime COLD & FLU RELIEF

Active ingredients (in each softgel)

DAYTIME SEVERE COLD AND FLU

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Guaifenesin 200 mg

Phenylephrine HCl 5mg

Active ingredients (in each softgel)

NIGHTTIME SEVERE COLD AND FLU

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Doxylamine succinate 6.25 mg

Phenylephrine HCl 5mg

Purpose

DAYTIME SEVERE COLD AND FLU

Pain reliever/fever reducer

Cough suppressant

Expectorant

Nasal decongestant

Purposes

NIGHTTIME SEVERE COLD AND FLU

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Nasal decongestant

Uses

DAYTIME SEVERE COLD AND FLU RELIEF

- temporarily relieves common cold/flu symptoms:
 - nasal congestion
 - sinus congestion & pressure
 - cough due to minor throat & bronchial irritation
 - minor aches & pains
 - headache
 - fever
 - sore throat
- reduces swelling of nasal passages
 - temporarily restores freer breathing through the nose
 - promotes nasal and/or sinus drainage
 - helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

Uses

NIGHTTIME SEVERE COLD AND FLU RELIEF

- temporarily relieves common cold/flu symptoms:
 - nasal congestion
 - sinus congestion & pressure
 - cough due to minor throat & bronchial irritation
 - cough to help you sleep
 - minor aches & pains
 - headache
 - fever
 - sore throat
 - runny nose & sneezing
- reduces swelling of nasal passages
 - temporarily restores freer breathing through the nose
 - promotes nasal and/or sinus drainage

Warnings

Liver warning

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

- more than 4 doses in 24 hrs, 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

DAYTIME SEVERE COLD AND FLU

- 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.

Do not use

NIGHTTIME SEVERE COLD AND FLU

- 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.
- to make a child sleep

Ask a doctor before use if you have

DAYTIME SEVERE COLD AND FLU

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema

Ask a doctor before use if you have

NIGHTTIME SEVERE COLD AND FLU

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema
- trouble urinating due to enlarged prostate gland

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

Ask a doctor or pharmacist before use if you are

- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin

When using this product, do not use more than directed.

When using this product

- **do not use more than directed**
- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, and tranquilizers may increase drowsiness

Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- pain, nasal congestion, or cough 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.

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

Keep out of reach of children.

Overdose warning

Taking more than directed can cause serious health problems. 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

- take only as directed - see Overdose warning
- do not exceed 4 doses per 24 hrs

adults & children 12 yrs and over	2 softgels with water every 4 hrs
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

- **when using other Nighttime or Daytime products, carefully read each label to ensure correct dosing**

Other information

- store at room temperature and avoid excessive heat

Inactive ingredients

DAYTIME SEVERE COLD AND FLU

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

Inactive ingredients**NIGHTTIME SEVERE COLD AND FLU**

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

Questions or comments?

Call toll free: 1-855-215-8180

Principal Display Panel

CVS Daytime COLD & FLU RELIEF and Nighttime COLD & FLU RELIEF

NDC 51013-117-04

*Compare to the active ingredients in Vicks® DayQuil® Severe and NyQuil® Severe Cold and Flu

CONTINUOUS
EFFECT

DAYTIME SEVERE COLD AND FLU

Drug Facts (continued)

- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back or worsens with mucus or headache that lasts. These could be signs of a serious condition.

If pregnant or breastfeeding, ask a health professional before use. Keep out of reach of children.

Directions

Take only as directed—see Directions warning.

Do not exceed 4 doses per 24 hrs.

adults & children 12 yrs & over	2 softgels with water every 4 hrs
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

When using other Nighttime or Daytime products, carefully read each label to ensure correct dosing.

Other information

- Store at room temperature 15°-40°C (59°-104°F) and avoid excessive heat.

Inactive ingredients FDAC yellow #6, polyethylene glycol, polyethylene glycol, polyethylene glycol, purified water, sodium acetate solution and white wax.

Questions or comments? Call toll free: 1-888-215-4710

"This product is not manufactured or distributed by Pfizer & Sonnet, owner of the registered trademarks "Severe", "Daytime", "Nighttime", "Severe Cold & Flu" and "Severe" "Severe" "Severe Cold & Flu".

Manufactured by: CVS Pharmacy, Inc., 10000 North Meridian, #10000, Dallas, TX 75243, USA
© 2014 CVS Health
CVS Health™ 1-888-215-4710
Made in China 144727

CVS Quality
How Good We Feel

201303-01

NIGHTTIME SEVERE COLD AND FLU

Drug Facts (continued)

- be careful when driving a motor vehicle or operating machinery
- dizziness, lightheadedness, and blurred vision may increase drowsiness

Top uses and side effects:

- use for cough, sleep or sore throat
- pain, nasal congestion, or cough 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 worsens with mucus or headache that lasts. These could be signs of a serious condition.

If pregnant or breastfeeding, ask a health professional before use. Keep out of reach of children.

Directions

Take only as directed—see Directions warning.

Do not exceed 4 doses per 24 hrs.

adults & children 12 yrs & over	2 softgels with water every 4 hrs
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

When using other Nighttime or Daytime products, carefully read each label to ensure correct dosing.

Other information

- Store at room temperature 15°-40°C (59°-104°F) and avoid excessive heat.

NIGHTTIME SEVERE COLD AND FLU

Drug Facts (continued)

Inactive ingredients FDAC yellow #6, polyethylene glycol, polyethylene glycol, polyethylene glycol, purified water, sodium acetate solution and white wax.

Questions or comments? Call toll free: 1-888-215-4710

CONTINUOUS
EFFECT

CVS Health.

Severe Daytime
COLD & FLU RELIEF

CVS Health.

Severe Nighttime
COLD & FLU RELIEF

Compare to the active ingredients in "Severe" Daytime Cold & Flu Relief

CVS Health.

Severe Daytime
COLD & FLU RELIEF

Active ingredients: Acetaminophen, Pseudoephedrine HCl, Dextromethorphan HBr, Carbinoxamine HCl, Phenylephrine HCl, and Tripropylene Glycol.

Compare to the active ingredients in "Severe" Nighttime Cold & Flu Relief

CVS Health.

Severe Nighttime
COLD & FLU RELIEF

Active ingredients: Acetaminophen, Diphenhydramine HCl, Dextromethorphan HBr, Carbinoxamine HCl, Phenylephrine HCl, and Tripropylene Glycol.

MAXIMUM STRENGTH

Full strength
Full strength
Full strength
Full strength
Full strength
Full strength

Actual Size

12 SOFTGELS

LOT NO: EXP DATE: CONTINUOUS EFFECT AREA

APR0488

0 50428 56613 4

THIS PRODUCT IS PACKAGED IN A CHILD RESISTANT AND TAMPER EVIDENT PACKAGE. USE ONLY IF INSTRUCTIONS ARE STRICTLY FOLLOWED.

PARENTS:
www.DrugMedicineSafety.org

DO NOT TAKE THESE PRODUCTS AT THE SAME TIME

DAYTIME SEVERE COLD AND FLU

Drug Facts

Active ingredients (in each softgel)	Purpose
Acetaminophen 325 mg	Pain relief/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Pseudoephedrine 200 mg	Decongestant
Phenylephrine HCl 5 mg	Nasal decongestant

Uses

- temporarily relieves common cold/flu symptoms
- nasal congestion
- sinus congestion & pressure
- sore throat
- relief of nasal passages
- temporarily relieves fever breathing through the nose
- helps loosen phlegm (mucus) and thin bronchial secretions to aid the bronchial passages of better mucus and make cough more productive.

Warnings

Use warning: This product contains acetaminophen. Severe liver damage may occur if you take more than 4 doses in 24 hrs, which is the maximum daily amount for this product.

● with other drugs containing acetaminophen

● or more alcohol drinks every day while using this product

NIGHTTIME SEVERE COLD AND FLU

Drug Facts

Active ingredients (in each softgel)	Purpose
Acetaminophen 325 mg	Pain relief/fever reducer
Diphenhydramine HCl 10 mg	Cough suppressant
Dextromethorphan HBr 10 mg	Cough suppressant
Phenylephrine HCl 5 mg	Nasal decongestant

Uses

- temporarily relieves common cold/flu symptoms
- nasal congestion
- sinus congestion & pressure
- sore throat
- relief of nasal passages
- temporarily relieves fever breathing through the nose
- helps loosen phlegm (mucus) and thin bronchial secretions to aid the bronchial passages of better mucus and make cough more productive.

Warnings

Use warning: This product contains acetaminophen. Severe liver damage may occur if you take more than 4 doses in 24 hrs, which is the maximum daily amount for this product.

● with other drugs containing acetaminophen

● or more alcohol drinks every day while using this product

See first warning: 1 case of liver failure, possibly fatal, has been reported in a child who took more than 2 doses of this product in 24 hours. It is accompanied or followed by fever, weakness, pain, nausea, or vomiting, consult a doctor promptly.

DAYTIME SEVERE COLD & FLU

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.

Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema

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

When using this product, do not use more than directed.

Stop use and ask a doctor if ■ you get nervous, dizzy or sleepless ■ pain, nasal congestion, or cough gets worse or lasts more than 7 days ▼

NIGHTTIME SEVERE COLD & FLU

Drug Facts (continued)

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.
- to make a child sleep

Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema
- trouble urinating due to enlarged prostate gland

Ask a doctor or pharmacist before use if you are

- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin

When using this product

- do not use more than directed
- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, and tranquilizers may increase drowsiness ▼

CVS DAYTIME COLD AND FLU RELIEF AND NIGHTTIME COLD AND FLU RELIEF

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:510 13-117
--------------	----------------	--------------------	----------------

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:510 13-117-04	1 in 1 CARTON; Type 0: Not a Combination Product	06/30/2016	

Quantity of Parts

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

Part 1 of 2

CVS DAYTIME COLD AND FLU RELIEF

acetaminophen, dextromethorphan hydrobromide, guaifenesin, 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
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	5 mg

Inactive Ingredients

Ingredient Name	Strength
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)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	orange (clear)	Score	no score
Shape	capsule (oblong)	Size	26mm
Flavor		Imprint Code	PC26
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	06/30/2016	

Part 2 of 2

CVS NIGHTTIME COLD AND FLU RELIEF

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
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	5 mg

Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	green	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		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	06/30/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/30/2016	

Labeler - PuraCap Pharmaceutical LLC (962106329)

Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceuticals (Wuhan) Co., Ltd		421293287	manufacture(510 13-117) , analysis(510 13-117)

Revised: 1/2020

PuraCap Pharmaceutical LLC