

**DAYTIME AND NIGHTTIME SEVERE COLD AND FLU DAYTIME NON DROWSY NIGHTTIME- acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride / acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride**  
**CVS PHARMACY**

*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.*

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**CVS Health Non-Drowsy Daytime Severe Cold & Flu and Nighttime Severe Cold & Flu**

**DAYTIME SEVERE COLD AND FLU**

**Drug Facts**

<b>Active ingredients (in each softgel)</b>	<b>Purposes</b>
Acetaminophen 325 mg.....	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg.....	Cough suppressant
Guaifenesin 200 mg.....	Expectorant
Phenylephrine HCl 5 mg.....	Nasal decongestant

**Uses**

- 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.

**Warnings**

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

- more than 4 doses 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

**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.

**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.

### **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.**

### **Drug Facts** (continued)

#### **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 hours

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

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

## Other information

- store at room temperature

## Inactive ingredients

FD&C Yellow # 6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan, titanium dioxide

NIGHTTIME SEVERE COLD & FLU SOFTGELS

## Drug Facts

### Active ingredients (in each softgel)

### Purposes

Acetaminophen 325 mg.....	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg.....	Cough suppressant
Doxylamine succinate 6.25 mg.....	Antihistamine
Phenylephrine HCl 5 mg.....	Nasal decongestant

## Uses

- 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 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  
If a skin 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.

## **NIGHTTIME SEVERE COLD & FLU SOFTGELS**

### **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.
- 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

## **NIGHTTIME SEVERE COLD & FLU SOFTGELS**

### **Drug Facts** (continued)

#### **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 hours

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

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#### **Other information**

store at room temperature

#### **Inactive ingredients**

D&C Yellow No. 10, FD&C Blue No. 1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan, sodium hydroxide†, titanium dioxide

It may contain this ingredient

**Questions or comments?**

**Call toll free: 1-888-333-9792**

**PRINCIPAL DISPLAY PANEL**

**CVS Health** Compare to the active ingredients in Vicks® Day-Quil® Severe Cold & Flu\*

**CVS Health** Compare to the active ingredients in Vicks® NyQuil® Severe Cold & Flu\*

**Non-Drowsy**  
**Severe Daytime**  
**COLD & FLU RELIEF**  
ACETAMINOPHEN  
Pain reliever/Fever reducer  
DEXTROMETHORPHAN HBr  
Cough suppressant  
GUAIFENESIN  
Expectorant  
PHENYLEPHRINE HCl  
Nasal decongestant  
**MAXIMUM STRENGTH**  
Relieves:  
Aches; Fever; Cough; Nasal congestion; Sore throat; Chest congestion  
Alcohol free  
Antihistamine free  
Actual Size  
**12 SOFTGELS**

**Severe Nighttime**  
**COLD & FLU RELIEF**  
ACETAMINOPHEN  
Pain reliever/Fever reducer  
DEXTROMETHORPHAN HBr  
Cough suppressant  
DOXYLAMINE SUCCINATE  
Antihistamine  
PHENYLEPHRINE HCl  
Nasal decongestant  
**MAXIMUM STRENGTH**  
Relieves:  
Aches; Fever; Sore throat; Cough; Sneezing; Runny nose; Nasal/Sinus congestion & Sinus pressure  
Actual Size  
**12 SOFTGELS 24 TOTAL**

**DAYTIME AND NIGHTTIME SEVERE COLD AND FLU DAYTIME NON DROWSY NIGHTTIME**

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

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69842-818
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## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-818-24	1 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	08/25/2021	

## Quantity of Parts

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

## Part 1 of 2

### DAYTIME SEVERE COLD AND FLU DAYTIME NON-DROWSY

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
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg

## Inactive Ingredients

Ingredient Name	Strength
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE K30 (UNII: U725QWY32X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	orange (Light Orange)	<b>Score</b>	no score
<b>Shape</b>	OVAL (OBLONG)	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	341;908
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 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	08/25/2021	

## Part 2 of 2

### NIGHTTIME SEVERE COLD AND FLU

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

## Product Information

<b>Route of Administration</b>	ORAL
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## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
<b>DOXYLAMINE SUCCINATE</b> (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	



<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)
<b>POVIDONE K30</b> (UNII: U725QWY32X)
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)
<b>WATER</b> (UNII: 059QF0KO0R)
<b>SORBITOL</b> (UNII: 506T60A25R)
<b>SORBITAN</b> (UNII: 6O92ICV9RU)
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)

### Product Characteristics

<b>Color</b>	green	<b>Score</b>	no score
<b>Shape</b>	OVAL (OBLONG)	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	116;A07
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 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	08/25/2021	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/25/2021	

**Labeler** - CVS PHARMACY (062312574)

Revised: 11/2021

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