

**DAYTIME AND NIGHTTIME- acetaminophen, guaifenesin, dextromethorphan  
hbr, doxylamine succinate  
CVS HEALTH CORP**

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**CVS 916T Daytime and Nighttime**

***Daytime Cold & Flu Softgels***

***Drug Facts***

***Active ingredients (in each softgel)***

**Acetaminophen 325mg**

Guaifenesin 200mg

***Purposes***

**Pain reliever/fever reducer**

Cough suppressant

***Uses***

- Temporarily relieves these common cold and flu symptoms:
  - minor aches and pains
  - headache
  - sore throat
  - helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
  - temporarily reduces fever

***Warnings***

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

- more than 12 softgels in 24 hours, which is the maximum daily amount for this product
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily 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.

### **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.

### **Ask a doctor before use if you have**

- liver disease
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough that occurs with too much phlegm (mucus)

**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**

- pain 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 the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away (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 directed (see Overdose warning)**
- do not take more than 12 softgels in any 24-hour period
- adults and children 12 years of age and over: take 2 softgels every 4 hours
- children under 12 years of age: do not use

### **Other information**

- store at 20-25°C (68-77°F)
- avoid excessive heat

### **Inactive ingredients**

FD&C blue no. 1, gelatin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution, titanium dioxide

**Questions or comments?** Call **1-877-290-4008**

## **Nighttime Cold & Flu Softgels**

### **Drug Facts**

## ***Active ingredients (in each softgels)***

### **Acetaminophen 325 mg**

Dextromethorphan HBr

Doxylamine succinate 6.25 mg

## ***Purposes***

### **Pain reliever/fever reducer**

Cough suppressant

Antihistamine

## ***Uses***

- temporarily relieves these common cold and flu symptoms:
  - cough
  - minor aches and pains
  - sore throat
  - headache
  - runny nose
  - sneezing
  - itching of the nose or throat
  - itchy, watery eyes due to hay fever
- temporarily reduces fever
- controls cough to help you get to sleep headache

## ***Warnings***

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

- more than 12 softgels in 24 hours, which is the maximum daily amount for this product
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily 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.

**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
- glaucoma
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- cough that occurs with too much phlegm (mucus)

**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 use more than directed**
- excitability may occur, especially in children
- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- use caution when driving a motor vehicle or operating machinery

**Stop use and ask a doctor if**

- pain 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 the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away (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 directed (see Overdose warning)**
- do not take more than 12 softgels in any 24-hour period
- adults and children 12 years of age and over: take 2 softgels every 4 hours
- children under 12 years of age: do not use

## Other information

- store at 20-25°C (68-77°F)
- avoid excessive heat

## Inactive ingredients

D&C yellow no. 10, FD&C blue no. 1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, shellac, sorbitol sorbitan solution, titanium dioxide

**Questions or comments? Call 1-877-290-4008**

**CVS 916T**



## DAYTIME AND NIGHTTIME

acetaminophen, guaifenesin, dextromethorphan hbr, doxylamine succinate kit

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51316-961
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-961-24	1 in 1 CARTON; Type 0: Not a Combination Product	04/01/2026	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	2 BLISTER PACK	8 in 2
Part 2	2 BLISTER PACK	16 in 2

## Part 1 of 2

### NIGHTTIME

acetaminophen, dextromethorphan hbr, doxylamine succinate capsule, liquid filled

#### Product Information

**Item Code (Source)** NDC:51316-906

**Route of Administration** ORAL

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<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>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

#### Inactive Ingredients

Ingredient Name	Strength
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>SHELLAC</b> (UNII: 46N107B71O)	
<b>SORBITOL SOLUTION</b> (UNII: 8KW3E207O2)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITAN</b> (UNII: 6O921CV9RU)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>GELATIN, UNSPECIFIED</b> (UNII: 2G86QN327L)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	

#### Product Characteristics

<b>Color</b>	green	<b>Score</b>	no score
<b>Shape</b>	OVAL (Oblong shaped capsule)	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	191
<b>Contains</b>			

#### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		4 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 Drug	M012	04/01/2026	

## Part 2 of 2

### DAYTIME

acetaminophen, guaifenesin capsule, liquid filled

## Product Information

Item Code (Source)	NDC:51316-940
Route of Administration	ORAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>SHELLAC</b> (UNII: 46N107B710)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>GELATIN, UNSPECIFIED</b> (UNII: 2G86QN327L)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>SORBITOL SOLUTION</b> (UNII: 8KW3E207O2)	
<b>SORBITAN</b> (UNII: 6O92ICV9RU)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	

## Product Characteristics

Color	blue	Score	no score
Shape	OVAL (Oblong shaped capsule)	Size	20mm
Flavor		Imprint Code	190
Contains			

## Packaging

Item	Marketing Start	Marketing End
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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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 Drug	M012		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	04/01/2026	

**Labeler** - CVS HEALTH CORP (062312574)

**Registrant** - TIME CAP LABORATORIES, INC. (037052099)

### Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	manufacture(51316-961)

Revised: 3/2026

CVS HEALTH CORP