

**DAYTIME NIGHTTIME SEVERE COLD AND FLU- acetaminophen,  
dextromethorphan hbr, guaifenesin, doxylamine succinate, phenylephrine hcl  
CVS HEALTH CORP**

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**627T CVS Daytime Nighttime Severe Cold and Flu**

***Daytime Severe Cold and Flu - Drug Facts***

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

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Guaifenesin 200 mg

Phenylephrine HCl 5 mg

***Purpose***

Pain reliever/fever reducer

Cough suppressant

Expectorant

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 8 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
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**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.**

**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.** 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**

- take only as directed
- do not exceed 8 softgels per 24 hrs

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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

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**Other information**

- do not exceed 25°C

**Inactive ingredients** FD&C blue #1, FD&C red #40, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, shellac, sorbitol sorbitan solution, titanium dioxide

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

**Nighttime Severe Cold and Flu - Drug Facts****Active ingredients (in each softgel)**

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Doxylamine succinate 6.25 mg

Phenylephrine HCl 5 mg

**Purpose**

Pain reliever/fever reducer

Cough suppressant

Antihistamine

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 8 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

**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
- 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

**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.

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**Other information**

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**Inactive ingredients** FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, shellac, sorbitol sorbitan solution, titanium dioxide

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

Compare to active ingredients in Vicks® DayQuil® Severe Cold & Flu and Vicks® NyQuil® Severe Cold & Flu LiquiCaps™\*

Maximum Strength

NDC XXXXX-XXX-XX

# Daytime Nighttime Severe Cold & Flu

## Acetaminophen

(Pain Reliever / Fever Reducer)

Dextromethorphan HBr

(Cough Suppressant)

Phenylephrine HCl

(Nasal Decongestant)

Guaifenesin

(Expectorant)

- Headache, fever, sore throat, minor aches and pains
- Cough
- Chest congestion, thins and loosens mucus
- Nasal congestion, sinus pressure



Actual Size  
16 Daytime  
Softgels

## Acetaminophen

(Pain Reliever / Fever Reducer)

Dextromethorphan HBr

(Cough Suppressant)

Doxylamine Succinate

(Antihistamine)

Phenylephrine HCl

(Nasal Decongestant)

- Headache, fever, sore throat, minor aches and pains
- Cough
- Sneezing, runny nose
- Nasal congestion, sinus pressure
- Nighttime relief



Actual Size  
8 Nighttime  
Softgels

16 SOFTGELS

24 TOTAL SOFTGELS

8 SOFTGELS

## DAYTIME NIGHTTIME SEVERE COLD AND FLU

acetaminophen, dextromethorphan hbr, guaifenesin, doxylamine succinate, phenylephrine hcl kit

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:51316-527

### Packaging

Marketing Start

Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-527-24	2 in 1 CARTON	02/01/2025	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

### Quantity of Parts

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

### Part 1 of 2

#### DAYTIME SEVERE COLD AND FLU

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl capsule

### Product Information

Item Code (Source)	NDC:51316-525
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>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>SHELLAC</b> (UNII: 46N107B71O)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	

## Product Characteristics

Color	orange	Score	no score
Shape	BULLET	Size	16mm
Flavor		Imprint Code	73
Contains			

## Packaging

#	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	02/01/2025	

## Part 2 of 2

### NIGHTTIME SEVERE COLD AND FLU

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl capsule

## Product Information

Item Code (Source)	NDC:51316-526
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>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>SHELLAC</b> (UNII: 46N107B71O)	



<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>SORBITOL</b> (UNII: 506T60A25R)	

### Product Characteristics

<b>Color</b>	green	<b>Score</b>	no score
<b>Shape</b>	BULLET	<b>Size</b>	16mm
<b>Flavor</b>		<b>Imprint Code</b>	72
<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	02/01/2025	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	02/01/2025	

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

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

### Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LTD		925822975	manufacture(51316-527)