

**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

**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

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

**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
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- 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
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**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**

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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, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, shellac, sorbitol sorbitan solution, titanium dioxide

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

**627T 24ct**

SAFETY SEALED; DO NOT USE IF THE INDIVIDUAL CLUSTER UNIT IS OPEN OR TORN  
RETAIN CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

\*This product is not manufactured or distributed by The Procter & Gamble Company, none of the registered trademarks listed: DayQuil® Severe Cold & Flu LiquiCaps™ and NyQuil® Severe Cold & Flu LiquiCaps™.

Varnish Omit Area

**Drug Facts (continued)**

**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
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**Other information**

- do not exceed 25°C

**Inactive ingredients**

FDAC blue #1, FDAC red #40, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbic acid, sorbitol sorbitan solution, titanium dioxide

**Questions or comments?**  
Call 1-877-250-4008



**Maximum Strength! DAYTIME SEVERE COLD & FLU**  
Acetaminophen, 325 mg  
Pain Reliever, Fever Reducer  
Dextromethorphan HBr, 10 mg  
Cough Suppressant  
Guaifenesin, 200 mg  
Expectorant  
Phenylephrine HCl, 5 mg  
Nasal Decongestant

**Maximum Strength! NIGHTTIME SEVERE COLD & FLU**  
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

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

Thins & Loosens Mucus  
Relieves: Headache, Fever, Sore throat, Minor aches & pains, Cough, Chest congestion, Nasal congestion, sinus pressure

Nighttime Relief  
Relieves: Headache, Fever, Sore throat, Minor aches & pains, Cough, Sneezing, Runny nose, Nasal congestion, sinus pressure

**16 SOFTGELS**  
**24 TOTAL SOFTGELS**

**8 SOFTGELS**  
**Under OTC monograph.**

**Drug Facts** **Nighttime Severe Cold & Flu**

**Active ingredients (in each softgel)**

Active ingredients	Purpose
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 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 fever breaking 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 alcohol drinks every day while using this product

**Allergy alert:** Acetaminophen may cause severe skin reactions. Symptoms may include: skin redness, 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 at occurs with smoking, asthma, chronic bronchitis, or emphysema
- trouble urinating due to enlarged prostate gland

**Directions**

Take only as directed

- do not exceed 8 softgels 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

**Other information**

- do not exceed 25°C

**Inactive ingredients**

FDAC blue #1, FDAC red #40, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbic acid, sorbitol sorbitan solution, titanium dioxide

**Questions or comments?**  
Call 1-877-250-4008

**Drug Facts (continued)**

**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
- irritation 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.** 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.

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  - fever
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**Questions or comments?**  
Call 1-877-250-4008

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PAPER BOX MULTICARTON TRAY

627T 48ct

SAFETY SEALED: DO NOT USE IF THE INDIVIDUAL BLISTER UNIT IS OPEN OR TORN  
 RETAIN CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION  
 \*This product is not manufactured or distributed by The Procter & Gamble Company, maker of the registered trademarks Advil, Tylenol, Severe Cold & Flu LiquiCaps™ and NyQuil Severe Cold & Flu LiquiCaps™.



**Maximum Strength! DAYTIME SEVERE COLD & FLU**  
 Acetaminophen, 325 mg  
 Pain Reliever, Fever Reducer  
 Dextromethorphan HBr, 10 mg  
 Cough Suppressant  
 Guaifenesin, 200 mg  
 Expectorant  
 Phenylephrine HCl, 5 mg  
 Nasal Decongestant

**Maximum Strength! NIGHTTIME SEVERE COLD & FLU**  
 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

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

Thins & Loosens Mucus  
 Relieves: Headache, Fever, Sore throat, Minor aches & pains, Cough, Chest congestion, Nasal congestion, Sinus pressure

Nighttime Relief  
 Relieves: Headache, Fever, Sore throat, Minor aches & pains, Cough, Sneezing, Runny nose, Nasal congestion, Sinus pressure

32 SOFTGELS  
 48 TOTAL SOFTGELS

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 www.StopMedicineAbuse.org

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#178420  
 FPO 80%  
 UPC# 050428316993  
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Varnish Omit Area

**Drug Facts (continued)**  
 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 drowsy  
 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 (1-800-222-2222). 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  
 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

**Other information**  
 do not exceed 25°C

**Inactive ingredients**  
 FDAC blue #1, FDAC red #40, polyvinyl alcohol, polyethylene glycol, polyethylene glycol, purified water, sorbitol, sorbitol sorbitan solution, titanium dioxide

**Questions or comments?**  
 Call 1-877-238-4008

**Drug Facts (continued)**  
 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  
 drowsiness may occur, especially in children  
 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 drowsy  
 pain, nasal congestion, or cough gets worse or lasts more than 7 days  
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**Drug Facts (continued)**  
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Varnish Omit Area

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# 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				
#	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		
2	NDC:51316-527-48	4 in 1 CARTON	02/01/2025	
2		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: 9D2RTI9KYH) (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>SORBITOL</b> (UNII: 506T60A25R)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>SHELLAC</b> (UNII: 46N107B710)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	

#### 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: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
<b>DOXYLAMINE SUCCINATE</b> (UNII: V9B19B5YI2) (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 LIMITED		925822975	manufacture(51316-527)

Revised: 3/2026

CVS HEALTH CORP