#### DAYTIME AND NIGHTTIME HIGH BLOOD PRESSURE COLD AND FLU LIQUIDacetaminophen, dextromethorphan hbr and acetaminophen, dextromethorphan hbr, doxylamine succinate CVS Pharmacy, Inc.

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CVS 666L Daytime & Nighttime High Blood Pressure Cold and Flu Liquid

# Drug Facts Daytime High Blood Pressure Cold & Flu

#### Active ingredients (in each 30 mL)

Acetaminophen 650 mg

Dextromethorphan HBr 20 mg

#### Purpose

Pain reliever/fever reducer

Cough suppressant

Uses temporarily relieves common cold/flu symptoms:

- cough due to minor throat and bronchial irritation
- sore throat
- headache
- minor aches and pains
- fever

#### Warnings

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

- more than 4 doses (30 mL each dose) 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
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema

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

#### Stop use and ask a doctor if

- pain or cough get worse or last 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 (1-800-222-1222) 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
- only use the dose cup provided
- do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over	30 mL per dose every 4 hrs
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

#### Other information

- each 30 mL contains: sodium 30 mg
- store at no greater than 25°C and do not refrigerate

*Inactive ingredients* anhydrous citric acid, FD&C yellow no. 6, flavors, glycerin, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium citrate, sodium saccharin, sorbitol solution, sucralose, xanthan gum

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

# Nighttime High Blood Pressure Cold & Flu

# Active ingredients (in each 30 mL)

Acetaminophen 650 mg

Dextromethorphan HBr 30 mg

Doxylamine succinate 12.5 mg

# Purpose

Pain reliever/fever reducer

Cough suppressant

# Antihistamine

**Uses** temporarily relieves common cold/flu symptoms:

- cough due to minor throat and bronchial irritation
- sore throat
- headache
- minor aches and pains
- fever
- runny nose and sneezing

# Warnings

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

- more than 4 doses (30 mL each dose) 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
- 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

- 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

- 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.** In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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
- only use the dose cup provided
- do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over	30 mL per dose every 6 hrs
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

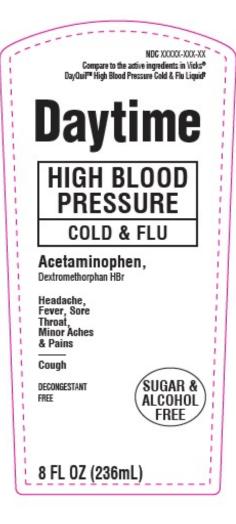
# Other information

- each 30 mL contains: sodium 30 mg
- store at no greater than 25°C and do not refrigerate

*Inactive ingredients* anhydrous citric acid, FD&C blue no. 1, FD&C red no. 40, flavors, glycerin, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium citrate, sodium saccharin, sorbitol solution, sucralose, xanthan gum

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





Compare to the active ingredients in Vicks<sup>®</sup> DayQuil™/NyQuil™ High Blood Pressure Cold & Flu Liquid<sup>†</sup>
NDC XXXX-XXX-XX

DAY &	
NIGHT	
PACK	

**Daytime** HIGH BLOOD PRESSURE

**COLD & FLU** 

Acetaminophen, Dextromethorphan HBr

Headache, Fever, Sore Throat, Minor Aches & Pains

Cough

DECONGESTANT FREE

# SUGAR & ALCOHOL FREE Nighttime HIGH BLOOD PRESSURE COLD & FLU

Acetaminophen, Doxylamine Succinate, Dextromethorphan HBr

Headache, Fever, Sore Throat, Minor Aches & Pains

Sneezing, Runny Nose Cough

Nighttime Relief DECONGESTANT FREE

2 BOTTLES - 1 DAYTIME/1 NIGHTTIME; 8 FL OZ (236 mL) EACH; TOTAL 16 FL OZ (472 mL)

# DAYTIME AND NIGHTTIME HIGH BLOOD PRESSURE COLD AND FLU LIQUID

acetaminophen, dextromethorphan hbr and acetaminophen, dextromethorphan hbr, doxylamine succinate kit

Produ	uct Infor	mation				
Produ	ct Type	HUMAN OT	C DRUG	Item Code	e (Source)	NDC:51316-666
Packa	aging					
# Ite	m Code	Packa	age Descriptio	'n	Marketing Start Date	Marketing End Date
<b>1</b> NDC: 07	51316-666-	1 in 1 PACKAGE; Product	Type 0: Not a Com	bination	04/21/2025	
Quan	tity of Pa	arts				
Part #		Package Qua	ntity		Total Product Q	)up ntity

Part 1	1 BOTTLE	236 mL
Part 2	1 BOTTLE	236 mL

# Part 1 of 2

# NIGHTTIME HIGH BLOOD PRESSURE COLD AND FLU

acetaminophen, dextromethorphan hbr, doxylamine succinate liquid

Inactive Ingredients

ltem Code (Source)	NDC:51316-664
Route of Administration	ORAL

#### **Active Ingredient/Active Moiety**

Ingredient Name	<b>Basis of Strength</b>	Strength
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 30 mL
<b>DOXYLAMINE SUCCINATE</b> (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	650 mg in 30 mL

Strength

mactive mgreatents	
Ingredient Name	
WATER (UNII: 059QF0K00R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM SACCHARIN (UNII: SB8ZUX40TY)	

ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)Image: Comparison of the comparison o

<b>Product Charac</b>	teristics	
Color	red (Clear red color solution)	Score
Shape		Size
Flavor	CHERRY	Imprint Code
Contains		

Packaging						
# Item Code	Pa	ckage Description	Mark	eting Start Date	Mark	eting End Date
<b>1</b> NDC:51316-664- 06	236 mL in 1 BC Product	OTTLE; Type 0: Not a Combination				
Marketing	Informat	ion				
			Mar	kating Ctart	Mari	kating End
Marketing Category	Арриса	tion Number or Monograph Citation	Mar	keting Start Date	Mari	keting End Date
OTC Monograph Dru	ug M012		04/21/	2025		
Part 2 of 2						
DAYTIME H	IGH BLO	OD PRESSURE COLD	AND	FLU		
		orphan hbr liquid		•		
sector mopricity	, achaionnean					
Product Infor	mation					
ltem Code (Sou	rce)	NDC:51316-665				
Route of Admini	istration	ORAL				
Route of Admini	istration	ORAL				
Route of Admini	istration	ORAL				
	ient/Active			Basis of Stre	ength	Strengt
Active Ingredi	ient/Active Ingred	Moiety	-L9D) A		ength	Strengt 650 mg in 30 mL
Active Ingredi Acetaminophen	ient/Active Ingred (UNII: 36209ITL	Moiety Jient Name	C	ACETAMINOPHEN DEXTROMETHORPI	-	650 mg in 30 mL 20 mg
Active Ingredi ACETAMINOPHEN DEXTROMETHORP	ient/Active Ingred (UNII: 36209ITL PHAN HYDROB	Moiety Jient Name 9D) (ACETAMINOPHEN - UNII:36209IT ROMIDE (UNII: 9D2RTI9KYH)	C	ACETAMINOPHEN	-	650 mg in 30 mL
Active Ingredi ACETAMINOPHEN DEXTROMETHORP	ient/Active Ingred (UNII: 36209ITL PHAN HYDROB	Moiety Jient Name 9D) (ACETAMINOPHEN - UNII:36209IT ROMIDE (UNII: 9D2RTI9KYH)	C	ACETAMINOPHEN DEXTROMETHORPI	-	650 mg in 30 mL 20 mg
Active Ingredi ACETAMINOPHEN DEXTROMETHORPH (DEXTROMETHORPH	ient/Active Ingred (UNII: 36209ITL PHAN HYDROBI AN - UNII:7355X	Moiety Jient Name 9D) (ACETAMINOPHEN - UNII:36209IT ROMIDE (UNII: 9D2RTI9KYH)	C	ACETAMINOPHEN DEXTROMETHORPI	-	650 mg in 30 mL 20 mg
Active Ingredi ACETAMINOPHEN DEXTROMETHORPH (DEXTROMETHORPH	ient/Active Ingred (UNII: 36209ITL PHAN HYDROBI AN - UNII:7355X	Moiety Jient Name 9D) (ACETAMINOPHEN - UNII:36209IT ROMIDE (UNII: 9D2RTI9KYH) 3ROTS)	C	ACETAMINOPHEN DEXTROMETHORPI	HAN	650 mg in 30 mL 20 mg in 30 mL
Active Ingredi ACETAMINOPHEN DEXTROMETHORPH (DEXTROMETHORPH Inactive Ingre	ient/Active Ingred (UNII: 36209ITL PHAN HYDROBI AN - UNII:7355X	Moiety Jient Name 9D) (ACETAMINOPHEN - UNII:36209IT ROMIDE (UNII: 9D2RTI9KYH)	C	ACETAMINOPHEN DEXTROMETHORPI	HAN	650 mg in 30 mL 20 mg
Active Ingredi ACETAMINOPHEN	ient/Active Ingred (UNII: 36209ITL PHAN HYDROBI AN - UNII:7355X edients	Moiety Jient Name 9D) (ACETAMINOPHEN - UNII:36209IT ROMIDE (UNII: 9D2RTI9KYH) 3ROTS) Ingredient Name	C	ACETAMINOPHEN DEXTROMETHORPI	HAN	650 mg in 30 mL 20 mg in 30 mL
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Froduct char	acteristics		
Color	orange (Clear orange color solution)	Score	
Shape		Size	
Flavor	CITRUS	Imprint C	ode
Contains			
Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
	236 mL in 1 BOTTLE; Type 0: Not a Combination Product		
• 06	Floddet		
Marketing	Information		
		Marketing Start Date	Marketing End Date
Marketing Marketing Category	Information Application Number or Monograph Citation		
Marketing Marketing Category OTC Monograph Dre	Information Application Number or Monograph Citation	Date	
Marketing Marketing Category OTC Monograph Dre	Information Application Number or Monograph Citation	Date	

Labeler - CVS Pharmacy, Inc. (062312574)

Registrant - Time Cap Laboratories, Inc. (037052099)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
MARKSANS PHARMA LIMITED		677604129	manufacture(51316-666)

Revised: 2/2025

CVS Pharmacy, Inc.