#### CVS DAYTIME COLD AND FLU RELIEF AND NIGHTTIME COLD AND FLU RELIEFacetaminophen, dextromethorphan hydrobromide, doxylamine succinate, guaifenesin, phenylephrine hydrochloride CVS PHARMACY, INC.

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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## Daytime COLD & FLU RELIEF and Nighttime COLD & FLU RELIEF

# Active ingredients (in each softgel)

## DAYTIME SEVERE COLD AND FLU

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Guaifenesin 200 mg

Phenylephrine HCl 5mg

# Active ingredients (in each softgel)

# NIGHTTIME SEVERE COLD AND FLU

Acetaminophen 325 mg Dextromethorphan HBr 10 mg Doxylamine succinate 6.25 mg Phenylephrine HCl 5mg

#### Purpose

# DAYTIME SEVERE COLD AND FLU

Pain reliever/fever reducer

Cough suppressant

Expectorant

Nasal decongestant

## Purposes

# NIGHTTIME SEVERE COLD AND FLU

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Nasal decongestant

# Uses DAYTIME SEVERE COLD AND FLU RELIEF

- 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

#### Uses

## NIGHTTIME SEVERE COLD AND FLU RELIEF

- 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 hrs, 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

#### 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.

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.

#### Do not use

## DAYTIME SEVERE COLD AND FLU

- 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.

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## NIGHTTIME SEVERE COLD AND FLU

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- to make a child sleep

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

#### DAYTIME SEVERE COLD AND FLU

- 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 before use if you have

## NIGHTTIME SEVERE COLD AND FLU

- 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 the blood thinning drug warfarin.

## 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.

#### 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.

#### 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 hrs

adults & children 12 yrs and over	2 softgels with water every 4 hrs
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

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

#### Other information

• store at room temperature and avoid excessive heat

#### **Inactive ingredients**

#### DAYTIME SEVERE COLD AND FLU

FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol special, and white edible ink

#### **Inactive ingredients**

# NIGHTTIME SEVERE COLD AND FLU

FD&C blue #1, D&C yellow #10, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol special, and white edible ink

# Questions or comments?

Call toll free: 1-855-215-8180

# Principal Display Panel - Carton Label

CVS Daytime COLD & FLU RELIEF and Nighttime COLD & FLU RELIEF

NDC 69842-070-04

\*Compare to the active ingredients in Vicks<sup>®</sup> DayQuil<sup>®</sup> Severe and NyQuil<sup>®</sup> Severe Cold and Flu



DAYTIME SEVERE COLD AND FLU	H CHITTIME SEVERE COLD AND FLU
Drag Facts (continued)	Drag Facts (continued)
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astima, choose termotilia, or emphysions Ask a declar or pharmaciel before use if you are taking the Need thinking drug warfalls,	Ask a declar or pharmacial before use if you are failing sadalises or transpillings failing the blood thinning drug warfarts
When using this product, do not use more than directed, Plap are and ank a doctor II poor part nermon, diazy or skepters pith, mod composition, or recept pots warse or facts more then 7 days	When using this product do not use more than directed contability may occur, especially in children marked describers may occur maind apoletic direks.

# CVS DAYTIME COLD AND FLU RELIEF AND NIGHTTIME COLD AND FLU RELIEF

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

Product Information							
Product Type	roduct Type HUMAN OTC DRUG			Item Code (Source)		NDC:69842-070	
Packaging							
# Item Code		Package Description	e Description Marketing Start l			ate Marketing End Date	
1 NDC:69842-070-04	1 in 1 CARTO	N; Type 0: Not a Combi	nation Product	12/13/2016			
Quantity of Parts	5						
Part #	Package Qu	iantity		Total F	Product Qua	antity	
art 1 BLISTER PACK			12				
	Part 2 1 BLISTER PACK						
Part 2 1 BLISTER PA	СК		12				
Part 2 1BLISTER PA	СК		12				
Part 1 of 2 CVS DAYTIN	IE COLD	AND FLU REL	ЛЕF				
Part 1 of 2 CVS DAYTIN	IE COLD	<b>AND FLU REL</b> an hydrobromide, gu	ЛЕF	nylephrine h	ydrochloride	e capsule, l	iquid filled
Part 1 of 2 CVS DAYTIN	IE COLD		ЛЕF	nylephrine h	ydrochloride	e capsule, l	iquid filled
Part 1 of 2 CVS DAYTIN	<b>IE COLD</b> xtromethorph		ЛЕF	nylephrine h	ydrochloride	e capsule, l	iquid filled
<b>Part 1 of 2</b> <b>CVS DAYTIN</b> acetaminophen, de	<b>IE COLD</b> xtromethorph t <b>ion</b>		ЛЕF	nylephrine h	ydrochloride	e capsule, l	iquid filled
Part 1 of 2 CVS DAYTIN acetaminophen, de Product Informa	<b>IE COLD</b> xtromethorph t <b>ion</b>	an hydrobromide, gu	ЛЕF	nylephrine h	ydro chlo ride	e capsule, l	iquid filled
Part 1 of 2 CVS DAYTIN acetaminophen, de Product Informa	<b>1E COLD</b> xtromethorph <b>tion</b> ation	an hydrobromide, gu ORAL	ЛЕF	nylephrine h	ydro chlo ride	e capsule, l	iquid filled
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Part 1 of 2 CVS DAYTIN acetaminophen, de Product Informa Route of Administr	IE COLD xtromethorph tion ation tt/Active Mo Ing	an hydrobromide, gu ORAL <b>ie ty</b>	J <b>EF</b> Jaifenesin, pher			trength	iquid filled Strength 325 mg

GUAIFENESIN (I	INII: 495	W7451VO) (G	UAIFENESIN - UNII:4	495W7451VO)	<b>GUAIFENES IN</b>	200 mg
				) (PHENYLEPHRINE -		
UNII:1WS297W6N		O CHLO KIDI	2 (ONII. 045A35 1135)	) (FILEIVILLEFFIKLIVE -	PHENYLEPHRINE	5 mg
Inactive Ingr	edient	S				
			Ingredient	Name		Strength
FD&C YELLOW	NO.6 (	UNII: H77VEI9	3A8)			
GELATIN (UNII:	2G86QN	I327L)				
GLYCERIN (UNI	I: PDC6A	3C0OX)				
POLYETHYLEN	E GLYC	OL, UNSPEC	IFIED (UNII: 3WJQ05	SDW1A)		
PO VIDO NE (UNI	II: FZ989	GH94E)				
PROPYLENE GL	LYCOL (	UNII: 6DC9Q	167V3)			
SORBITOL (UN	II: 506T6	0 A25R)				
WATER (UNII: 05	59QF0K0	00R)				
Product Cha	racteri	stics				
Color		orange (clea	ır)	Score		no score
Shape		capsule (obl	ong)	Size		26 mm
Flavor				Imprint (	Code	PC26
Contains						
<ul><li># Item Code</li><li>1</li></ul>	1 in 1 CA	RTON	kage Description		Marketing Start Date	Marketing End Date
		RTON	<b>kage Description</b> ; Type 0: Not a Com		Marketing Start Date	Marketing End Date
<ul> <li># Item Code</li> <li>1</li> <li>1</li> </ul>	12 in 1 B	RTON LISTER PACK	0		Marketing Start Date	Marketing End Date
<ul> <li># Item Code</li> <li>1</li> <li>1</li> <li>Marketing</li> </ul>	12 in 1 B	RTON LISTER PACK ' <b>mation</b>	; Type 0: Not a Com	bination Product		
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<ul> <li># Item Code</li> <li>1</li> <li>1</li> <li>Marketing</li> </ul>	12 in 1 B Infor tegory	RTON LISTER PACK ' <b>mation</b>	; Type 0: Not a Com	bination Product	Marketing Start Date	
# Item Code 1 1 Marketing Cat	12 in 1 B Infor egory final	RTON LISTER PACK <b>'mation</b> Applicatio	; Type 0: Not a Com	bination Product	Marketing Start Date	
<pre># Item Code 1 1 1 Marketing Marketing Cat OTC monograph</pre>	12 in 1 B Infor egory final	RTON LISTER PACK <b>'mation</b> Applicatio part341	; Type 0: Not a Com	bination Product	Marketing Start Date	
# Item Code          1         1         1         Marketing         Marketing Cat         OTC monograph         Part 2 of 2         CVS NIGH         acetaminopher	12 in 1 B Infor egory final	RTON LISTER PACK Mation Applicatio part341	; Type 0: Not a Com on Number or Mon D AND FLU	ograph Citation RELIEF	Marketing Start Date	Marketing End Date
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# Item Code          1         1         1         Marketing         Marketing Cat         OTC monograph         Part 2 of 2         CVS NIGH         acetaminopher         liquid filled	12 in 1 B Infor egory final ITTIN h, dextro	RTON LISTER PACK Mation Applicatio part341	; Type 0: Not a Com on Number or Mon D AND FLU	ograph Citation RELIEF	Marketing Start Date 12/13/2016	Marketing End Date
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# Item Code          1         1         1         Marketing         Marketing Cat         OTC monograph         Part 2 of 2         CVS NIGH         acetaminopher         liquid filled	12 in 1 Bi	INTON LISTER PACK Mation Applicatio part341 ME COL omethorpha	on Number or Mon D AND FLU I n hydrobromide, o	ograph Citation RELIEF	Marketing Start Date 12/13/2016	Marketing End Date

		Ingredient Name		Basis of Stre	ngth	Strength
ACETAMINO PH	IEN (UNII:	362O9ITL9D) (ACETAMINOP	HEN - UNII:362O9ITL9D)	ACETAMINOPHEN		325 mg
		HYDROBROMIDE (UNII: 9D2 UNII:7355X3ROTS)	DEXTROMETHORPHA HYDROBROMIDE	AN	10 mg	
DOXYLAMINE	SUCCINA	<b>TE</b> (UNII: V9BI9B5YI2) (DOXY	DOXYLAMINE SUCC	INATE	6.25 mg	
PHENYLEPHRIN UNII:1WS297W6		DCHLORIDE (UNII: 04JA59T)	PHENYLEPHRINE		5 mg	
Inactive Ing	redients	3				
		Ingredie	nt Name		St	rength
		JNII: 35SW5USQ3G)				
FD&C BLUE NO	,	,				
GELATIN (UNII:		,				
GLYCERIN (UN		,				
		DL, UNSPECIFIED (UNII: 3WJ	Q0SDW1A)			
POVIDONE (UN						
		UNII: 6DC9Q167V3)				
WATER (UNII: 0 SORBITOL (UN	-					
Product Cha	racteris	stics				
			S corro			
Color		green	Score		no score 20mm	
Color Shape			Size		20 mm	
Color Shape Flavor		green				
Color Shape Flavor Contains		green	Size		20 mm	
Color Shape Flavor Contains <b>Packaging</b>		green capsule (oblong)	Size Imprint Code	eting Start Date N	20 mm PC22	End Date
Color Shape Flavor Contains Packaging # Item Code	1 in 1 CA	green capsule (oblong) Package Descript	Size Imprint Code	eting Start Date N	20 mm PC22	; End Date
Color Shape Flavor Contains Packaging I Ltem Code	1 in 1 CAI	green capsule (oblong) Package Descript	ion Mark	eting Start Date N	20 mm PC22	End Date
Color Shape Flavor Contains Packaging I Item Code	1 in 1 CAI	green capsule (oblong) Package Descript	ion Mark	eting Start Date M	20 mm PC22	; End Date
Color Shape Flavor Contains Packaging # Item Code 1	1 in 1 CAl 12 in 1 BI	green capsule (oblong) Package Descript RTON LISTER PACK; Type 0: Not a C	ion Mark	eting Start Date N	20 mm PC22	; End Date
Color Shape Flavor Contains Packaging # Item Code 1	1 in 1 CAI 12 in 1 BI	green capsule (oblong) Package Descript RTON LISTER PACK; Type 0: Not a C	ion Mark		20mm PC22	
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Color Shape Flavor Contains Packaging # Item Code 1 1 Marketing Ca OTC monograph	1 in 1 CA 12 in 1 BI 5 Infor tegory final p 5 Infor	green capsule (oblong) Package Descript RTON LISTER PACK; Type 0: Not a C mation Application Number or Mo part341	ion Mark ombination Product	keting Start Date	20 mm PC22 Marketing	; End Date
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Labeler - CVS PHARMACY, INC. (062312574)

Establishment						
Name	Address	ID/FEI	Business Operations			
Humanwell PuraCap Pharmaceuticals (Wuhan) Co., Ltd		421293287	manufacture(69842-070) , analysis(69842-070)			

Revised: 11/2019

CVS PHARMACY, INC.