CVS DAYTIME AND NIGHTTIME VALUE PACK COLD AND FLU- acetaminophen, phenylephrine hydrochloride, and doxylamine succinate CVS PHARMACY

CVS DayTime & NightTime Cold & Flu Combo pack

DayTime Cold & Flu

Active ingredients (in each 30 mL)

Acetaminophen 650 mg Dextromethorphan HBr 20 mg Guaifenesin 400 mg Phenylephrine HCl 10 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 4 doses in 24 hours, which is the maximum daily amount for this product
- taken 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 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. 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 every 4 hours
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

Other information

each 30 mL contains:

- sodium 81 mg
- store at room temperature
- Do not refrigerate.

Inactive ingredients

Citric acid, D&C Yellow No. 10, disodium edetate, FD&C Blue No.1, flavor, glycerin, propyl gallate, propylene glycol, purified water, sodium benzoate, sodium chloride, sodium citrate, sorbitol, sucralose

Questions?

1-866-467-2748

NIGHTTIME COLD & FLU RELIEF

Active ingredients (in each caplet)

Acetaminophen 650 mg Dextromethorphan HBr 20 mg Doxylamine succinate 12.5 mg Phenylephrine HCl 10 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 4 doses in 24 hours, which is the maximum daily amount for this product
- taken 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.
- to make a child sleep

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 & 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. 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 every 4 hours
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

Other information

- each 30 mL contains: sodium 81 mg
- Store at room temperature
- Do not refrigerate

Inactive ingredients

Citric acid, D&C Yellow No. 10, disodium edetate, FD&C Blue No.1, flavor, glycerin, propyl gallate, propylene glycol, purified water, sodium benzoate, sodium chloride, sodium citrate, sorbitol, sucralose

Questions?

1-866-467-2748

Distributed By:

PRINCIPAL DISPLAY PANEL - Kit Carton

**Compare to the active ingredients in Vicks®DayQuil[™] Severe+ VapoCOOL[™]

NDC# 51316-156-24

DayTime

Cold & Flu

Relief

Acetaminophen - Pain reliever/Fever reducer

Dextromethorphan HBr - Cough suppressant

Guaifenesin - Expectorant

Phenylephrine HCI - Nasal decongestant

For Relief of

- Minor Aches & Pains, Fever
- Nasal Congestion & Sinus Pressure
- Cough
- Chest Congestion

*Compare to the active ingredients in Vicks®NyQuil[™] Severe+ VapoCOOL[™]

NightTime

Cold & Flu

Relief

Acetaminophen - Pain reliever/Fever reducer

Dextromethorphan HBr – Cough suppressant

Phenylephrine HCI - Antihistamine

Phenylephrine HCI - Nasal decongestant

For Relief of

- Minor Aches & Pains, Fever
- Nasal Congestion & Sinus Pressure
- Sneezing, Runny Nose
- Cough

TWO BOTTLES, 12 FL OZ (354 mL) each; TOTAL 24 FL OZ (708 mL)

**This product is not manufactured or distributed by Procter & Gamble, distributor of Vicks®Dayquil[™] Severe+ VapoCOOL[™] and Vicks® Nyquil[™] Severe+ VapoCOOL[™]

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	COLD & FLU TWO 12 FL OZ (354 mL) UNITS	COLD & FLU TOTAL 24 FL OZ (708 mL)	Drug Foto (part Branch Sector (part Branch Sector (part Branch Sector (part) Charles (part) Charle	watch is a state - table is concerning a state - table is a state - table - table is a state - table - tab	These active the product on concerning with the deck. They are and active concerning with the deck w	E INSULTS	ar sollar Frig er S. K., solar adal, 1 M. Ar Syste, wird aatsisten S. Sollege

CVS DAYTIME AND NIGHTTIME VALUE PACK COLD AND FLU

acetaminophen, phenylephrine hydrochloride, and doxylamine succinate kit

Produ	ict Infori	nation					
Produc	ct Type	HUMAN	OTC DRUG	OTC DRUG Item Code (Source)		NDC:51316-156	
Packa	aina						
	m Code	Pa	ckage Descriptio	'n	Marketing Start Date	Marketing End Date	
1 NDC: 24	51316-156-	1 in 1 PACKAO Product	GE; Type 0: Not a Com	bination	03/10/2023		
Quant	tity of Pa	arts					
Part #		Package (Quantity	uantity Total Product (
Part 1	1 BOTTLE			354 mL			
Part 2	1 BOTTLE			354 mL			
Part	1 of 2						
CVS DAYTIME COLD AND FLU acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride liquid							
Produ	ict Infori	mation					
ltem C	ode (Sour	ce)	NDC:51316-412				
Route	of Adminis	stration	ORAL				

Active Ingredient/Active Moiety						
Ingredient Name	Basis of Strength	Strength				
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D)	ACETAMINOPHEN	650 mg in 30 mL				
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 30 mL				
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 30 mL				
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS 297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 30 mL				

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1		354 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC Monograph Drug	M012	03/10/2023	

Part 2 of 2

CVS NIGHTTIME COLD AND FLU

acetaminophen, phenylephrine hydrochloride, doxylamine succinate, and dextromethorphan hydrobromide liquid

Product Information	on					
ltem Code (Source)	NDO	0:51316-712				
Route of Administrati	ion OR/	AL.				
Active Ingredient/A	Active Mo	iety				
	Ingredien	t Name		Basis of Stre	ength	Strength
ACETAMINOPHEN (UNII: 3	362O9ITL9D)	(ACETAMINOPHEN -	UNII:36209ITL9	D) ACETAMINOPHEN		650 mg in 30 mL
DEXTROMETHORPHAN H (DEXTROMETHORPHAN - UN	DEXTROMETHORPH HYDROBROMIDE	DEXTROMETHORPHAN HYDROBROMIDE				
DOXYLAMINE SUCCINATI UNII:95QB77JKPL)	E (UNII: V9BI	9B5YI2) (DOXYLAMIN	IE -	DOXYLAMINE SUCC	INATE	12.5 mg in 30 mL
PHENYLEPHRINE HYDRO UNII:1WS297W6MV)	CHLORIDE (UNII: 04JA59TNSJ) (P	HENYLEPHRINE	- PHENYLEPHRINE HYDROCHLORIDE		10 mg in 30 mL
Inactive Ingredient						
		ngredient Nam	е			Strength
ANHYDROUS CITRIC ACI						
D&C YELLOW NO. 10 (UN		· · ·				
EDETATE DISODIUM (UNI						
FD&C BLUE NO. 1 (UNII: H)				
GLYCERIN (UNII: PDC6A3C						
PROPYL GALLATE (UNII: 8						
PROPYLENE GLYCOL (UN WATER (UNII: 059QF0K00F		v5)				
· ·	-	1)				
SODIUM BENZOATE (UNII	-					
SODIUM CHLORIDE (UNII:						
SODIUM CITRATE, UNSPI			ILR)			
SORBITOL (UNII: 506T60A	-					
SUCRALOSE (UNII: 96K6U0	Q3ZD4)					
Packaging						
# Item Code	Packa	ge Description	T	Aarketing Start Date		eting End Date
1 NDC:51316-712- 354 ml 12 Produc		E; Type 0: Not a Co	mbination	Date		Date
12 FIOUUC						
Marketing Info	rmatior					
		• Number or Mon Citation	ograph	Marketing Start Date	Marl	ceting End Date
OTC Monograph Drug M01	10		0	3/10/2023		
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Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC Monograph Drug	M012	03/10/2023	

Labeler - CVS PHARMACY (062312574)

Revised: 11/2023

CVS PHARMACY