# DAYTIME NIGHTTIME COLD FLU RELIEF- acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl CVS Pharmacy

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#### **Drug Facts**

### Active ingredients for Daytime (in each softgel)

#### Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

#### Active ingredients for Nighttime (in each softgel)

#### Acetaminophen 325 mg

Dextromethorphan HBr 15 mg

Doxylamine succinate 6.25 mg

#### **Purpose for Daytime**

#### Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

#### **Purpose for Nighttime**

#### Pain reliever/fever reducer

Cough suppressant

**Antihistamine** 

#### Uses

#### **DAYTIME**

- temporarily relieves common cold and flu symptoms
  - cough due to minor throat and bronchial irritation
  - nasal congestion
  - headache
  - minor aches and pains
  - fever
  - sore throat

#### **NIGHTTIME**

- temporarily relieves common cold and flu symptoms
  - cough due to minor throat and bronchial irritation
  - sore throat
  - headache
  - minor aches and pains
  - fever
  - runny nose and sneezing

#### **Warnings**

#### **DAYTIME**

**Liver warning:** These products contain acetaminophen. Severe liver damage may occur if you take:

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using these products

**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.

#### **NIGHTTIME**

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

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Alergy 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 following by fever, headache, rash, nausea, vomiting, consult a doctor promptly.

#### Do not use

**DAYTIME** 

- 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.

#### **NIGHTTIME**

- 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

#### **DAYTIME**

- liver disease
- heart disease
- diabetes
- thyroid disease
- high blood pressure
- cough that occurs with too much phlegm (mucus)
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema

#### **NIGHTTIME**

- liver disease
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- trouble urinating due to an enlarged prostate gland

#### Ask a doctor or pharmacist before use if you are

#### DAYTIME

taking the blood thinning drug warfarin

#### **NIGHTTIME**

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

#### When using this product,

#### **DAYTIME**

do not use more than directed

#### **NIGHTTIME**

- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

#### Stop use and ask a doctor if

#### **DAYTIME**

- nervousness, dizziness or sleeplessness occur
- pain, cough, and nasal congestion gets worse or lasts more than 7 days
- redness or swelling is present
- new symptoms occur
- fever gets worse or lasts more than 3 days
- cough comes back or occurs with rash or headache that lasts. These could be signs
  of a serious condition.

#### **NIGHTTIME**

- 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 headache that lasts. These could be a 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 the recommended dose can cause liver damage. 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**

#### **DAYTIME**

- do not take more than directed (see Overdose warning)
- do not take more than 4 doses in 24 hours
- swallow whole; do not crush, chew, or dissolve
- adults and children 12 years and over; take 2 softgels with water every 4 hours.
- children under 12 years: do not use

#### NIGHTTIME

- do not take more than directed (see Overdose warning)
- · do not take more than 4 doses in 24 hours
- swallow whole; do not crush, chew, or dissolve

- adults and children 12 years and over: take 2 softgels with water every 6 hours
- children under 12 years: do not use

#### Other information

- store between 15-30°C (59-86°F)
- avoid excessive heat

#### Inactive ingredients

#### **DAYTIME**

butylated hydroxyanisole\*, butylated hydroxytoluene\*, carminic acid\*, D&C yellow #10\*, edible white ink, FD&C red #40\*, FD&C yellow #6\*, gelatin, glycerin, polyethylene glycol\*, povidone, propylene glycol, purified water, sodium metabisulfite\*, sorbitan\*, sorbitol,

\*contains one or more of these ingredients

#### **NIGHTTIME**

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

\*may contain this ingredient

#### Questions or comments?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

#### **Principal Display Panel**

Compare to the active ingredients in Vicks® DayQuil® and NyQuil® LiquiCaps®†

#### **DAYTIME**

Non-Drowsy, Multi-Symptom

Daytime COLD & FLU RELIEF

Acetaminophen - Pain reliever, Fever reducer

Dextromethorphan HBr - Cough suppressant

Phenylephrine HCI - Nasal decongestant

Relieves: Aches; Fever; Cough; Nasal congestion

ALCOHOL FREE

ANTIHISTAMINE FREE

LIQUID GELS

#### **NIGHTTIME**

Multi-Symptom

#### COLD & FLU RELIEF

Acetaminophen - Pain reliever, Fever reducer

Dextromethorphan HBr - Cough suppressant

Doxylamine succinate - Antihistamine

Relieves: Aches; Fever; Cough; Sore throat; Sneezing; Runny nose

LIQUID GELS

(Liquid filled capsules)

When using Daytime and Nighttime products, carefully read the labeling to ensure correct dosing.

†This product is not manufactured or distributed by The Procter & Gamble Company. Vicks®, DayQuil, NyQuil®, and LiquiCaps® are registered trademarks of the Procter and Gamble Company.

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOW SIGNS OF TAMPERING.

## KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Distributed by: CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

**Product Label** 





Compare to the active ingredients in Vicks® DayQuil® and NyQuil® LiquiCaps®†

NDC 59779-646-24



ACETAMINOPHEN

**DEXTROMETHORPHAN HBr** 

Cough suppressan

PHENYLEPHRINE HCI

Nasal decongestant

Aches; Fever; Cough; Nasal congestion

Alcohol free

## **Multi-Symptom COLD & FLU RELIEF**

#### **ACETAMINOPHEN**

Pain reliever; Fever reducer

**DEXTROMETHORPHAN HBr** 

Cough suppressant

DOXYLAMINE SUCCINATE

**Antihistamine** 

Aches; Fever; Cough; Sore throat; Sneezing; Runny nose



SIGNS OF TAMPERING COMPLETE WARNINGS AND IS OPENED OR IF **USE IF CARTON BROKEN OR SHOWS ANY CARTON FOR EVIDENT: DO** OUTER S

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#278531



CVS Daytime and Nighttime Cold & Flu Softgels

#### DAYTIME NIGHTTIME COLD FLU RELIEF

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl kit

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:59779-646

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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-646- 24	1 in 1 CARTON; Type 0: Not a Combination Product	04/30/2016	12/27/2024
2	NDC:59779-646- 48	1 in 1 CARTON; Type 0: Not a Combination Product	06/01/2016	

#### **Quantity of Parts**

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

#### Part 1 of 2

#### **NIGHTTIME COLD FLU RELIEF**

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate capsule

#### **Product Information**

**Route of Administration** 

ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg	
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg	

Inactive Ingredients	
Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ 989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6092ICV9RU)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics				
Color	green	Score	no score	
Shape	CAPSULE	Size	21mm	
Flavor		Imprint Code	P30;94A;215;P120	
Contains				

Pa	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1		16 in 1 CARTON			
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product			
2		8 in 1 CARTON			
2		1 in 1 BLISTER PACK; Type 0: Not a Combination Product			

Marketing Information					
MarketingApplication Number or MonographMarketing StartMarketing EndCategoryCitationDateDate					
OTC Monograph Drug	M012	04/30/2016	12/27/2024		

### Part 2 of 2

#### **DAYTIME COLD FLU RELIEF**

acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule

#### **Product Information**

Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg	

Inactive Ingredients			
Ingredient Name	Strength		
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)			
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
GELATIN (UNII: 2G86QN327L)			
GLYCERIN (UNII: PDC6A3C0OX)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
POVIDONE (UNII: FZ 989GH94E)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
SORBITAN (UNII: 6092ICV9RU)			
SORBITOL (UNII: 506T60A25R)			
CARMINIC ACID (UNII: CID8Z8N95N)			
SODIUM METABISULFITE (UNII: 4VON5FNS3C)			
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)			

Product Characteristics			
Color	orange	Score	no score
Shape	CAPSULE	Size	21mm
Flavor		Imprint Code	P19;95A;512;P119
Contains			

Packaging			
" Item	Dockowa Docavintian	Marketing Start	Marketing End

#	Code	Раскаде резсприон	Date	Date
1		16 in 1 CARTON		
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2		32 in 1 CARTON		
2		1 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	04/30/2016	12/27/2024					

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC Monograph Drug	M012	04/30/2016	12/27/2024			

### Labeler - CVS Pharmacy (062312574)

Revised: 3/2024 CVS Pharmacy