

**COLD AND FLU DAYTIME NIGHTTIME- acetaminophen, dextromethorphan hbr,  
doxylamine succinate, phenylephrine hcl  
CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED**

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**CVS 44-012013**

***Active ingredients (in each 15 mL)***

Acetaminophen 325 mg  
Dextromethorphan HBr 10 mg  
Phenylephrine HCl 5 mg

***Purpose***

Pain reliever/fever reducer  
Cough suppressant  
Nasal decongestant

***Uses***

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

***Warnings***

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

- adult takes more than 4,000 mg of acetaminophen in 24 hours
- child takes more than 5 doses in 24 hours
- taken with other drugs containing acetaminophen
- adult has 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.
- if you have ever had an allergic reaction to this product or any of its ingredients

**Ask a doctor before use if the user has**

- difficulty in urination due to enlargement of the prostate gland
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- heart disease
- diabetes
- thyroid disease
- liver disease
- high blood pressure

**Ask a doctor or pharmacist before use if the user is**

taking the blood thinning drug warfarin.

**When using this product**

**do not exceed recommended dosage.**

**Stop use and ask a doctor if**

- nervousness, dizziness, or sleeplessness occur
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- pain, nasal congestion, or cough gets worse or lasts more than 5 days (children) or 7 days (adults)
- 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. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

**Directions**

- **do not take more than directed**

- do not exceed 4 doses per 24 hours
- mL = milliliter
- only use the dose cup provided

adults and children 12 years and over	30 mL every 4 hours
children 6 to under 12 years	15 mL every 4 hours
children under 6 years	do not use

### ***Other information***

- **each 15 mL contains:** sodium 13 mg
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- use by expiration date on package

### ***Inactive ingredients***

anhydrous citric acid, FD&C yellow #6, flavors, glycerin, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium citrate dihydrate, sodium metabisulfite, sodium saccharin, sorbitol, sucralose

### ***Questions or comments?***

**1-800-426-9391**

### ***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 and flu symptoms:
  - headache
  - minor aches and pains
  - sore throat
  - runny nose and sneezing
  - cough due to minor throat and bronchial irritation
- temporarily reduces fever

## **Warnings**

**Liver warning:** This product contains 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

**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.
- if you have ever had an allergic reaction to this product or any of its ingredients

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

- difficulty in urination due to enlargement of the prostate gland
- cough that occurs with too much phlegm (mucus)
- liver disease
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema
- glaucoma

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

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

### **When using this product**

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

**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 right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

**Directions**

- **do not take more than directed**
- do not exceed 4 doses per 24 hours
- mL = milliliter
- only use the dose cup provided
- adults and children 12 years and over: 30 mL every 6 hours
- children under 12 years: do not use

**Other information**

- **each 30 mL contains:** sodium 13 mg
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- use by expiration date on package

**Inactive ingredients**

anhydrous citric acid, FD&C blue #1, FD&C red #40, flavor, glycerin, high fructose corn syrup, polyethylene glycol 400, propylene glycol, purified water, sodium benzoate, sodium chloride, sodium citrate dihydrate, sodium saccharin, sucralose

**Principal display panel**

COMBO PACK

♥CVS  
Health®  
Compare to the active  
ingredients in Vicks®  
DayQuil® Cold & Flu\*  
**Daytime**

♥CVS  
Health®  
Compare to the active  
ingredients in Vicks®  
NyQuil® Cold & Flu\*  
**Multi-Symptom**

**COLD & FLU  
ACETAMINOPHEN**

Pain reliever, Fever reducer  
DEXTROMETHORPHAN HBr  
Cough suppressant  
PHENYLEPHRINE HCl  
Nasal decongestant

Relieves:

Headache, Fever, Sore throat,  
Minor aches & pains,  
Nasal congestion,  
Sinus pressure,  
Cough  
Menthol  
Flavor

Ages 6 Years & Over

**2 - 12 FL OZ  
(355 mL) BOTTLES**

**Multisymptom**

**Nighttime  
COLD & FLU  
ACETAMINOPHEN**

Pain reliever, Fever reducer  
DEXTROMETHORPHAN HBr  
Cough suppressant  
DOXYLAMINE SUCCINATE  
Antihistamine

Relieves:

Headache, Fever,  
Sore throat, Minor aches  
& pains, Sneezing,  
Runny nose, Cough  
Cherry  
Flavor

Ages 12 Years & Over

**TOTAL 24 FL OZ  
(710 mL)**

**TAMPER EVIDENT: DO NOT USE IF PRINTED NECK WRAP IS BROKEN OR MISSING**

PARENTS:

Learn about teen medicine abuse  
[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)

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50844  
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**COMBO PACK**

**Drug Facts DAYTIME**

**Active ingredients (in each 15 mL)**  
Acetaminophen 325 mg  
Dextromethorphan HBr 10 mg  
Phenylephrine HCl 3 mg

**Purpose**  
Pain reliever  
Cough suppressant  
Nasal decongestant

**Uses**  
Temporarily relieves common cold and flu symptoms:  
● sore throat ● nasal congestion ● minor aches and pains  
● cough due to throat and bronchial irritation ● headache  
● temporarily reduces fever

**Warnings**  
● **Do not take more than 3000 mg of acetaminophen in 24 hours**  
● Do not take more than 5 doses in 24 hours  
● Do not take with other drugs containing acetaminophen  
● Do not take with other drugs containing dextromethorphan  
● Do not take with other drugs containing phenylephrine  
● Do not take with other drugs containing pseudoephedrine  
● Do not take with other drugs containing ephedrine  
● Do not take with other drugs containing propylhexedrine  
● Do not take with other drugs containing tramadol  
● Do not take with other drugs containing hydrocodone  
● Do not take with other drugs containing oxycodone  
● Do not take with other drugs containing hydroxyzine  
● Do not take with other drugs containing lorazepam  
● Do not take with other drugs containing alprazolam  
● Do not take with other drugs containing clonazepam  
● Do not take with other drugs containing diazepam  
● Do not take with other drugs containing gabapentin  
● Do not take with other drugs containing pregabalin  
● Do not take with other drugs containing tramadol  
● Do not take with other drugs containing hydrocodone  
● Do not take with other drugs containing oxycodone  
● Do not take with other drugs containing hydroxyzine  
● Do not take with other drugs containing lorazepam  
● Do not take with other drugs containing alprazolam  
● Do not take with other drugs containing diazepam  
● Do not take with other drugs containing gabapentin  
● Do not take with other drugs containing pregabalin

**Directions**  
● **Do not take more than directed**  
● Do not exceed 4 doses per 24 hours  
● **Do not use**  
● **Do not use**

**Other information**  
● **Do not take more than directed**  
● Do not exceed 4 doses per 24 hours  
● **Do not use**  
● **Do not use**

**Active ingredients**  
● **Do not take more than directed**  
● Do not exceed 4 doses per 24 hours  
● **Do not use**  
● **Do not use**

**Questions or comments?** 1-800-426-3931

**CVS Health.** Compare to the active ingredients in Vicks® DayQuil® Cold & Flu®

**CVS Health.** Compare to the active ingredients in Vicks® NyQuil® Cold & Flu®

**Daytime**

**Multi-Symptom Nighttime**

**COLD & FLU**

**COLD & FLU**

**ACETAMINOPHEN**  
Pain reliever, Fever reducer  
**DEXTROMETHORPHAN HBr**  
Cough suppressant  
**PHENYLEPHRINE HCl**  
Nasal decongestant

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

**2 - 12 FL OZ (355 mL) BOTTLES**

Ages 6 Years & Over

**ACETAMINOPHEN**  
Pain reliever, Fever reducer  
**DEXTROMETHORPHAN HBr**  
Cough suppressant  
**DOXYLAMINE SUCCINATE**  
Antihistamine

Relieves:  
Headache, Fever, Sore throat, Minor aches & pains, Sneezing, Runny nose, Cough

**TOTAL 24 FL OZ (710 mL)**

Ages 12 Years & Over

**Drug Facts NIGHTTIME**

**Active ingredients (in each 30 mL)**  
Acetaminophen 650 mg  
Dextromethorphan HBr 10 mg  
Doxylamine succinate 12.5 mg

**Purpose**  
Pain reliever  
Cough suppressant  
Antihistamine

**Uses**  
Temporarily relieves common cold and flu symptoms:  
● headache ● minor aches and pains  
● sore throat ● runny nose and sneezing  
● cough due to throat and bronchial irritation  
● temporarily reduces fever

**Warnings**  
● **Do not take more than 3000 mg of acetaminophen in 24 hours**  
● Do not take more than 5 doses in 24 hours  
● Do not take with other drugs containing acetaminophen  
● Do not take with other drugs containing dextromethorphan  
● Do not take with other drugs containing doxylamine  
● Do not take with other drugs containing phenylephrine  
● Do not take with other drugs containing pseudoephedrine  
● Do not take with other drugs containing ephedrine  
● Do not take with other drugs containing propylhexedrine  
● Do not take with other drugs containing tramadol  
● Do not take with other drugs containing hydrocodone  
● Do not take with other drugs containing oxycodone  
● Do not take with other drugs containing hydroxyzine  
● Do not take with other drugs containing lorazepam  
● Do not take with other drugs containing alprazolam  
● Do not take with other drugs containing diazepam  
● Do not take with other drugs containing gabapentin  
● Do not take with other drugs containing pregabalin

**Directions**  
● **Do not take more than directed**  
● Do not exceed 4 doses per 24 hours  
● **Do not use**  
● **Do not use**

**Other information**  
● **Do not take more than directed**  
● Do not exceed 4 doses per 24 hours  
● **Do not use**  
● **Do not use**

**Active ingredients**  
● **Do not take more than directed**  
● Do not exceed 4 doses per 24 hours  
● **Do not use**  
● **Do not use**

**Questions or comments?** 1-800-426-3931

**CVS 44-012013**

# COLD AND FLU DAYTIME NIGHTTIME

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl kit

Product Information	
<b>Product Type</b>	HUMAN OTC DRUG
<b>Item Code (Source)</b>	NDC:51316-123

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-123-02	1 in 1 PACKAGE; Type 0: Not a Combination Product	07/28/2023	

Quantity of Parts		
Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE, PLASTIC	355 mL
Part 2	1 BOTTLE, PLASTIC	355 mL

## Part 1 of 2

# COLD AND FLU DAYTIME

acetaminophen, dextromethorphan hbr, phenylephrine hcl solution

Product Information	
<b>Item Code (Source)</b>	NDC:51316-120
<b>Route of Administration</b>	ORAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg in 15 mL
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 15 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 15 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>TRISODIUM CITRATE DIHYDRATE</b> (UNII: B22547B95K)	
<b>SODIUM METABISULFITE</b> (UNII: 4VON5FNS3C)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	

## Product Characteristics

<b>Color</b>	orange	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MENTHOL	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-120-02	355 mL in 1 BOTTLE, PLASTIC; 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	07/28/2023	

## Part 2 of 2

## COLD AND FLU NIGHTTIME



acetaminophen, dextromethorphan hbr, doxylamine succinate solution

### Product Information

**Item Code (Source)** NDC:51316-130

**Route of Administration** ORAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 30 mL
<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

### Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>HIGH FRUCTOSE CORN SYRUP</b> (UNII: XY6UN3QB6S)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>TRISODIUM CITRATE DIHYDRATE</b> (UNII: B22547B95K)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	

### Product Characteristics

<b>Color</b>	red (MAROON)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-130-02	355 mL in 1 BOTTLE, PLASTIC; 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	07/28/2023	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	07/28/2023	

**Labeler** - CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED (062312574)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	manufacture(51316-123) , pack(51316-123)

Revised: 6/2024

CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED