

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

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
- marked drowsiness may occur
- avoid alcoholic beverages
- 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

NDC 51316-123-02

♥CVS™

Menthol Flavor
DAYTIME
COLD & FLU

Cherry Flavor
Multi-Symptom
NIGHTTIME

COLD & FLU**Acetaminophen**

Pain Reliever, Fever Reducer
 Dextromethorphan HBr
 Cough Suppressant
 Phenylephrine HCl
 Nasal Decongestant
 Compare to the active
 ingredients in Vicks®
 DayQuil™ Cold & Flu*

Multi-Symptom Relief:

Headache, Fever, Sore throat,
 Minor aches & pains, Nasal
 congestion, Cough

Ages 6 Years & Older**COLD & FLU****Acetaminophen**

Pain Reliever, Fever Reducer
 Dextromethorphan HBr
 Cough Suppressant
 Doxylamine Succinate
 Antihistamine
 Compare to the active
 ingredients in Vicks®
 NyQuil™ Cold & Flu*

Multi-Symptom Relief:

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

Ages 12 Years & Older**TWO—12 FL OZ (355 mL) BOTTLES / TOTAL 24 FL OZ (710 mL)****TAMPER EVIDENT: DO NOT USE IF PRINTED NECK WRAP IS BROKEN OR MISSING****Do Not Take Daytime and Nighttime Products at the Same Time.****PARENTS:**

Learn about teen medicine abuse
www.StopMedicineAbuse.org

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Route of Administration ORAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

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

Product Characteristics

Color	orange	Score	
Shape		Size	
Flavor	MENTHOL	Imprint Code	
Contains			

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
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 30 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 30 mL
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL

Inactive Ingredients

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

Product Characteristics

Color	red (MAROON)	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a		

130-02	Combination Product		
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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: 11/2025

CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED