

**SEVERE COLD AND FLU DAYTIME, NIGHTTIME- acetaminophen,
chlorpheniramine maleate, dextromethorphan hbr, guaifenesin,
phenylephrine hcl
CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED**

CVS 44-503A473C

Active ingredients (in each caplet) (daytime)

Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Guaifenesin 200 mg
Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer
Cough suppressant
Expectorant
Nasal decongestant

Active ingredients (in each caplet) (nighttime)

Acetaminophen 325 mg
Chlorpheniramine maleate 2 mg
Dextromethorphan HBr 10 mg
Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer
Antihistamine
Cough suppressant
Nasal decongestant

Uses

- temporarily relieves these common cold and flu symptoms:
 - minor aches and pains
 - headache
 - sore throat
 - cough
 - nasal congestion
 - sinus congestion and pressure
 - sneezing and runny nose (***nighttime only***)
- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive (***daytime only***)

- helps clear nasal passages
- relieves cough to help you sleep
- 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.

Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- 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, chronic bronchitis, or emphysema
- a breathing problem such as emphysema or chronic bronchitis (**nighttime only**)
- glaucoma (**nighttime only**)

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers (**nighttime only**)

When using this product

- **do not exceed recommended dosage**
- excitability may occur, especially in children (**nighttime only**)
- marked drowsiness may occur (**nighttime only**)
- alcohol, sedatives, and tranquilizers may increase drowsiness (**nighttime only**)
- avoid alcoholic beverages (**nighttime only**)
- use caution when driving a motor vehicle or operating machinery (**nighttime only**)

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- 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. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Do not take DAYTIME and NIGHTTIME products at the same time.

Directions

- **do not take more than directed**
- adults and children 12 years and over
 - take 2 caplets every 4 hours
 - swallow whole - do not crush, chew, or dissolve
 - do not take more than 10 caplets in 24 hours
- children under 12 years: ask a doctor

Other information

- **each caplet contains:** sodium 3 mg
- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

Inactive ingredients (daytime only)

corn starch, crospovidone, D&C yellow #10 aluminum lake, flavor, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone,

silicon dioxide, sodium starch glycolate, stearic acid, sucralose, talc, titanium dioxide

Inactive ingredients (nighttime only)

corn starch, crospovidone, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, flavor, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, sucralose, talc, titanium dioxide

Questions or comments?

1-800-426-9391

Principal display panel

NDC 51316-509-08



**Daytime
SEVERE COLD
& FLU**

Acetaminophen

Pain Reliever, Fever Reducer

Dextromethorphan HBr, Cough Suppressant

Guaifenesin, Expectorant

Phenylephrine HCl, Nasal Decongestant

**Nighttime
SEVERE COLD
& FLU**

Acetaminophen

Pain Reliever, Fever Reducer

Chlorpheniramine Maleate, Antihistamine

Dextromethorphan HBr, Cough Suppressant

Phenylephrine HCl, Nasal Decongestant

Compare to Tylenol® Cold + Flu Severe Day & Night active ingredients*

Relieves: Fever, Headache, Sore throat, Nasal & chest congestion, Cough, Mucus
16 CAPLETS
actual

size

Relieves: Fever, Headache, Sore throat, Runny nose, Cough, Nasal congestion
8 CAPLETS
actual

size

24 TOTAL CAPLETS

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

PARENTS:

**Learn about teen medicine abuse
www.StopMedicineAbuse.org**

Do Not Take Daytime and

**Nighttime Products at the
Same Time.**

*This product is not manufactured or distributed by Kenvue Inc.,
owner of the registered trademark Tylenol® Cold + Flu Severe
Day & Night.

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www.StuffedCapsules.org

Do Not Take Daytime and
Nighttime Products at the
Same Time.

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Drug Facts	Purpose
Active ingredients (in each caplet) (daytime) Acetaminophen 325 mg Dextromethorphan HBr 10 mg Guaifenesin 200 mg Phenylephrine HCl 5 mg	Pain reliever/fever reducer Cough suppressant Expectorant Nasal decongestant
Active ingredients (in each caplet) (nighttime) Acetaminophen 325 mg Chlorpheniramine maleate 2 mg Dextromethorphan HBr 10 mg Phenylephrine HCl 5 mg <td>Pain reliever/fever reducer Antihistamine Cough suppressant Nasal decongestant</td>	Pain reliever/fever reducer Antihistamine Cough suppressant Nasal decongestant
Uses temporarily relieves these common cold and flu symptoms: ■ minor aches and pains ■ sore throat ■ sinus congestion and pressure ■ sneezing and runny nose (nighttime only) ■ helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive (daytime only)	

PEEL HERE FOR MORE DRUG FACTS

CVS

Daytime
SEVERE COLD & FLU

16 CAPLETS

Nighttime
SEVERE COLD & FLU

8 CAPLETS

CVS

Daytime
SEVERE COLD & FLU

Acetaminophen
Pain Reliever, Fever Reducer
Dextromethorphan HBr, Cough Suppressant
Guaifenesin, Expectorant
Phenylephrine HCl, Nasal Decongestant

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Relieves: Fever, Headache, Sore throat,
Nasal & chest congestion, Cough, Mucus

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Nighttime
SEVERE COLD & FLU

Acetaminophen
Pain Reliever, Fever Reducer
Chlorpheniramine Maleate, Antihistamine
Dextromethorphan HBr, Cough Suppressant
Phenylephrine HCl, Nasal Decongestant

Relieves: Fever, Headache, Sore throat,
Runny nose, Cough, Nasal congestion

8 CAPLETS actual size

24 TOTAL CAPLETS

Drug Facts (continued)

- 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**
 - liver disease
 - heart disease
 - high blood pressure
 - thyroid disease
 - diabetes
 - 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, chronic bronchitis, or emphysema
 - a breathing problem such as emphysema or chronic bronchitis (nighttime only)
 - glaucoma (nighttime only)
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 - taking the blood thinning drug warfarin
 - taking sedatives or tranquilizers (nighttime only)

Drug Facts (continued)

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- use caution when driving a motor vehicle or operating machinery (nighttime only)

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- pain, nasal congestion, or cough gets worse or lasts more than 7 days
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- new symptoms occur
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If pregnant or breast-feeding, ask a health professional before use.

Drug Facts (continued)

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.

Do not take DAYTIME and NIGHTTIME products at the same time.

Directions

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 - do not take more than 10 caplets in 24 hours
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Other information

- each caplet contains: sodium 3 mg
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- see end flap for expiration date and lot number

Drug Facts (continued)

Inactive ingredients (daytime only)
corn starch, croscopolone, FD&C yellow #10 aluminum lake, flavor, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, sucralose, talc, titanium dioxide

Inactive ingredients (nighttime only)
corn starch, croscopolone, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, flavor, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, sucralose, talc, titanium dioxide

Questions or comments? 1-800-426-9391

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CVS 44-503A473C

SEVERE COLD AND FLU DAYTIME, NIGHTTIME

acetaminophen, chlorpheniramine maleate, dextromethorphan hbr, guaifenesin, phenylephrine hcl kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51316-509
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-509-08	1 in 1 CARTON; Type 0: Not a Combination Product	03/06/2026	

Quantity of Parts

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

Part 1 of 2

SEVERE COLD AND FLU DAYTIME

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl tablet, film coated

Product Information

Item Code (Source)	NDC:51316-555
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Route of Administration	ORAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
CROSPVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	yellow	Score	no score
Shape	OVAL	Size	19mm
Flavor	MENTHOL	Imprint Code	44;503
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 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	03/06/2026	

Part 2 of 2

SEVERE COLD AND FLU NIGHTTIME

acetaminophen, chlorpheniramine maleate, dextromethorphan hbr, phenylephrine hcl tablet, film coated

Product Information

Item Code (Source)	NDC:51316-556
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 mg
DEXTROMETHORPHAN HYDROBROMIDE (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
STARCH, CORN (UNII: O8232NY3SJ)	
CROSPVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
FD&C BLUE NO. 2 ALUMINUM LAKE (UNII: 4AQJ3LG584)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	blue	Score	no score
Shape	OVAL	Size	17mm
Flavor	MENTHOL	Imprint Code	44;473
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 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	03/06/2026	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	03/06/2026	

Labeler - CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED (062312574)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(51316-509) , pack(51316-509)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(51316-509)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(51316-509)

Revised: 3/2026

CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED