

**COLD AND FLU RELIEF NON-DROWSY / DAYTIME SEVERE / NIGHTTIME SEVERE-
acetaminophen, dextromethorphan hbr, doxylamine succinate, guaifenesin,
phenylephrine hcl
CVS Pharmacy**

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

CVS 44-640677 ND Delisted

Active ingredients (in each caplet) (Daytime Severe Cold & Flu)

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 Severe Cold & Flu)

Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Doxylamine succinate 6.25 mg
Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer
Cough suppressant
Antihistamine
Nasal decongestant

Uses

- temporarily relieves common cold and flu symptoms:
 - minor aches and pains
 - nasal congestion
 - headache
 - fever
 - sore throat

- sinus congestion and pressure
- cough due to minor throat and bronchial irritation
- runny nose and sneezing (**Nighttime only**)
- 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 (**Daytime only**)

Warnings

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

- with other drugs containing acetaminophen
- more than 4,000 mg of acetaminophen in 24 hours
- 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

- liver disease
- diabetes
- high blood pressure
- glaucoma (**Nighttime only**)
- thyroid disease
- heart disease
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, chronic

bronchitis, or emphysema (**Daytime only**)

- difficulty in urination due to enlargement of the prostate gland
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema (**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**)
- avoid alcoholic beverages (**Nighttime only**)
- be careful when driving a motor vehicle or operating machinery (**Nighttime only**)
- alcohol, sedatives, and tranquilizers may increase drowsiness (**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 accidental 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.

Read each section carefully. Do not take DAYTIME and NIGHTTIME products at the same time.

Directions

- **do not take more than directed**
- do not take more than 8 caplets of Daytime and Nighttime products in any 24-hour period
- adults and children 12 years and over: take 2 caplets with water every 4 hours
- children under 12 years: ask a doctor

Other information

- **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°C-30°C (59°F-86°F)
- see end flap for expiration date and lot number

Inactive ingredients (Daytime only)

corn starch, crospovidone, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polysorbate 80, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, talc, titanium dioxide

Inactive ingredients (Nighttime only)

black iron oxide, corn starch, crospovidone, D&C yellow #10 aluminum lake, FD&C blue #1 aluminum lake, FD&C yellow #6 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, talc, titanium dioxide

Questions or comments?

1-800-426-9391

Principal Display Panel

<div> <div>♥ CVS</div> <div>Health™</div> </div> <div> Compare to the active ingredients in Vicks® DayQuil® Severe Cold & Flu* </div>	<div> <div>♥ CVS</div> <div>Health™</div> </div> <div> Compare to the active ingredients in Vicks® NyQuil® Severe Cold Flu* </div>
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<div>Non-Drowsy</div> <div>Daytime</div> <div>Severe</div> <div>COLD & FLU RELIEF</div> <div>ACETAMINOPHEN</div> <div>Pain reliever/Fever reducer</div> <div>DEXTROMETHORPHAN HBr</div> <div>Cough suppressant</div> <div>GUAIFENESIN</div> <div>Expectorant</div> <div>PHENYLEPHRINE HCl</div> <div>Nasal decongestant</div> <div>MAXIMUM STRENGTH</div> <div>Relieves:</div> <div>Headache, fever, sore throat, minor aches & pains, nasal/ sinus congestion &</div>	<div>Nighttime</div> <div>Severe</div> <div>COLD & FLU RELIEF</div> <div>ACETAMINOPHEN</div> <div>Pain reliever/Fever reducer</div> <div>DEXTROMETHORPHAN HBr</div> <div>Cough suppressant</div> <div>DOXYLAMINE SUCCINATE</div> <div>Antihistamine</div> <div>PHENYLEPHRINE HCl</div> <div>Nasal decongestant</div> <div>MAXIMUM STRENGTH</div> <div>Relieves:</div> <div>Headache, fever, sore throat, minor aches & pains, nasal/ sinus congestion & sinus pressure,</div>
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sinus pressure, cough, chest congestion Actual Size 32 CAPLETS	sneezing, runny nose, cough Actual Size 16 CAPLETS 48 TOTAL
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**TAMPER EVIDENT: DO NOT USE IF
PACKAGE IS OPENED OR IF BLISTER
UNIT IS TORN, BROKEN OR SHOWS
ANY SIGNS OF TAMPERING**

*This product is not manufactured or distributed by The Procter & Gamble Company, owner of the registered trademark Vicks® DayQuil® Severe Cold & Flu and Vicks® NyQuil® Severe Cold & Flu.
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COLD AND FLU RELIEF NON-DROWSY / DAYTIME SEVERE / NIGHTTIME SEVERE

acetaminophen, dextromethorphan hbr, doxylamine succinate, guaifenesin, phenylephrine hcl kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-677
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-677-22	1 in 1 CARTON; Type 0: Not a Combination Product	08/01/2015	11/23/2024

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	4 BLISTER PACK	32

Part 1 of 2**COLD AND FLU RELIEF NON-DROWSY / DAYTIME SEVERE**

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

Product Information**Route of Administration** ORAL**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 (UNII: 2S7830E561)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
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)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	orange	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	44;640
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 final	part341	02/27/2014	

Part 2 of 2

COLD AND FLU RELIEF NIGHTTIME SEVERE

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl tablet, film coated

Product Information

Route of Administration ORAL

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
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSPVIDONE (UNII: 2S7830E561)	
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

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)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	green	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	44;677
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 final	part341	08/01/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/01/2015	11/23/2024

Labeler - CVS Pharmacy (062312574)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(59779-677)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	pack(59779-677)

Establishment

Name	Address	ID/FEI	Business Operations
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LNK International, Inc.		832867894	manufacture(59779-677)
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Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	pack(59779-677)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(59779-677)

Revised: 1/2023

CVS Pharmacy