

**SEVERE NIGHTTIME COLD AND FLU RELIEF- acetaminophen,  
dextromethorphan hbr, doxylamine succinate, phenylephrine hcl tablet, film  
coated  
Rite Aid Corporation**

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**Rite Aid 44-677**

***Active ingredients (in each caplet)***

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
  - sinus congestion and pressure
  - sore throat
  - fever
  - headache
  - nasal congestion
  - cough to help you sleep
  - runny nose and sneezing
  - cough due to minor throat and bronchial irritation
- reduces swelling of nasal passages
- promotes nasal and/or sinus drainage
- temporarily restores freer breathing through the nose

***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:

- blisters
- rash
- skin reddening

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
- thyroid disease
- heart disease
- glaucoma
- high blood pressure
- 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
- cough that occurs with too much phlegm (mucus)

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

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

### **When using this product**

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

### **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.

***Directions***

- **do not take more than directed**
- do not take more than 8 caplets in 24 hours
- adults and children 12 years and over: take 2 caplets with water every 4 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***

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***

NDC 11822-0677-8

Compare to the active ingredients in

**Vicks® NyQuil® VapoCOOL®  
SEVERE COLD & FLU + CONGESTION\***

**MAXIMUM STRENGTH**

**SEVERE NIGHTTIME**

## **COLD & FLU RELIEF**

**DEXTROMETHORPHAN HBr** - COUGH SUPPRESSANT

**DOXYLAMINE SUCCINATE** - ANTIHISTAMINE

**PHENYLEPHRINE HCl** - NASAL DECONGESTANT

**Relieves headache, fever, sore throat,  
minor aches & pains, nasal/sinus congestion  
& sinus pressure, sneezing, runny nose, cough**

### **Actual Size**

**24 CAPLETS**

**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® NyQuil® VapoCOOL® SEVERE COLD & FLU + CONGESTION.  
50844 REV0722C67708

**DISTRIBUTED BY: RITE AID,  
200 NEWBERRY COMMONS  
ETTERS, PA 17319  
[www.riteaid.com](http://www.riteaid.com)**

### **SATISFACTION GUARANTEE**

If you're not satisfied,  
we'll happily refund your money.



**SEVERE NIGHTTIME COLD AND FLU RELIEF**

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

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:11822-0677
<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
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
<b>DOXYLAMINE SUCCINATE</b> (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

**Inactive Ingredients**

Ingredient Name	Strength
<b>FERROSO FERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>CROSPVIDONE, UNSPECIFIED</b> (UNII: 2S7830E561)	
<b>D&amp;C YELLOW NO. 10 ALUMINUM LAKE</b> (UNII: CQ3XH3DET6)	
<b>FD&amp;C BLUE NO. 1 ALUMINUM LAKE</b> (UNII: J9EQA3S2JM)	
<b>FD&amp;C YELLOW NO. 6 ALUMINUM LAKE</b> (UNII: GYP6Z2JR6Q)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

**Product Characteristics**

<b>Color</b>	green	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	44;677

**Contains****Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-0677-8	2 in 1 CARTON	12/10/2019	
1		12 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	12/10/2019	

**Labeler** - Rite Aid Corporation (014578892)**Establishment**

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(11822-0677) , pack(11822-0677)

**Establishment**

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(11822-0677)

**Establishment**

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	manufacture(11822-0677)

**Establishment**

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(11822-0677)