

**SEVERE CONGESTION AND COUGH, COLD AND FLU NIGHTTIME-  
acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl,  
triprolidine hcl  
Walgreen Company**

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**Walgreens 44-004063-45**

***Active ingredients (in each 20 mL)***

Dextromethorphan HBr 20 mg

Guaifenesin 400 mg

Phenylephrine HCl 10 mg

***Purpose***

Cough suppressant

Expectorant

Nasal decongestant

***Uses***

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily relieves:
  - cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
  - the intensity of coughing
  - the impulse to cough to help you get to sleep
  - nasal congestion due to a cold

***Warnings***

**Do not use**

- 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**

- heart disease
- diabetes
- thyroid disease
- difficulty in urination due to enlargement of the prostate gland
- high blood pressure
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema

- cough that occurs with too much phlegm (mucus)

### **When using this product**

**do not exceed recommended dosage.**

### **Stop use and ask a doctor if**

- nervousness, dizziness, or sleeplessness occur
- symptoms do not get better within 7 days or occur with fever
- cough persists more than 7 days, tends to recur, or is accompanied by a fever, rash, or persistent headache. 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.

### ***Directions***

- **do not take more than directed**
- do not take more than 6 doses in any 24-hour period
- mL = milliliter
- only use the dose cup provided
- adults and children 12 years and over: 20 mL in dosing cup provided every 4 hours
- children under 12 years: do not use

### ***Other information***

- **each 20 mL contains:** sodium 9 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, flavors, glycerin, propylene glycol, purified water, sodium benzoate, sodium citrate dihydrate, sodium metabisulfite, sorbitol, sucralose, xanthan gum

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

**1-800-426-9391**

### ***Active ingredients (in each 20 mL)***

Acetaminophen 650 mg  
Dextromethorphan HBr 20 mg  
Triprolidine HCl 2.5 mg

## **Purpose**

Pain reliever/fever reducer  
Cough suppressant  
Antihistamine

## **Uses**

- temporarily relieves these common cold and flu symptoms:
  - cough
  - headache
  - runny nose
  - sneezing
  - sore throat
  - itching of the nose or throat
  - minor aches and pains
  - itchy, watery eyes due to hay fever
- temporarily reduces fever
- controls cough to help you get to sleep

## **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:

- rash
- blisters
- 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**

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

### **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
- 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
- new symptoms occur
- redness or swelling is present
- 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 4 doses in any 24-hour period
- mL = milliliter
- only use the dose cup provided
- adults and children 12 years and over: 20 mL in dosing cup provided every 4 hours
- children under 12 years: do not use

**Other information**

- 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, FD&C yellow #6, flavors, glycerin, propylene glycol, purified water, sodium benzoate, sucralose, xanthan gum

**Principal Display Panel**

**DAY & NIGHT PACK**

NDC 0363-4063-45

**Walgreens**

WALGREENS PHARMACIST RECOMMENDED†

Compare to the active ingredients in Mucinex® FAST-MAX® Severe Congestion & Cough & NIGHTSHIFT® Cold & Flu††

<p><b>Severe Congestion &amp; Cough</b>  <b>DEXTROMETHORPHAN HBr / COUGH SUPPRESSANT</b>  <b>GUAIFENESIN / EXPECTORANT</b>  <b>PHENYLEPHRINE HCl / NASAL DECONGESTANT</b>  Maximum Strength  • Controls cough  • Relieves nasal &amp; chest congestion  • Thins &amp; loosens mucus  • 12 years &amp; older</p>	<p><b>NIGHTTIME Cold &amp; Flu</b>  <b>ACETAMINOPHEN / PAIN RELIEVER / FEVER REDUCER</b>  <b>DEXTROMETHORPHAN HBr / COUGH SUPPRESSANT</b>  <b>TRIPROLIDINE HCl / ANTIHISTAMINE</b>  Multi-Symptom  • Relieves cough, fever, sore throat, runny nose &amp; sneezing  • 12 years &amp; older</p>
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**2 - 6 FL OZ (177 mL) BOTTLES / TOTAL 12 FL OZ (355 mL)**

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

**PARENTS:**

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

**Do not take Severe Congestion & Cough and Nighttime Cold & Flu at the same time.**

50844    ORG042300406345

†Our pharmacists recommend the Walgreens brand. We invite you to compare to national brands.

††This product is not manufactured or distributed by RB Health (US) LLC, owner of the registered trademarks Mucinex® FAST-MAX® Severe Congestion & Cough and NIGHTSHIFT® Cold & Flu.

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**Walgreens 44-004063**

# SEVERE CONGESTION AND COUGH, COLD AND FLU NIGHTTIME

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl, triprolidine hcl kit

Product Information			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0363-4063

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-4063-45	1 in 1 PACKAGE; Type 0: Not a Combination Product	10/23/2023	

Quantity of Parts			
Part #	Package Quantity		Total Product Quantity
Part 1	1 BOTTLE, PLASTIC		177 mL
Part 2	1 BOTTLE, PLASTIC		177 mL

## Part 1 of 2

### SEVERE CONGESTION AND COUGH

dextromethorphan hbr, guaifenesin, phenylephrine hcl solution

#### Product Information

Item Code (Source) NDC:0363-8004

Route of Administration ORAL

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 20 mL
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 20 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 20 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>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>SORBITOL</b> (UNII: 506T60A25R)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

#### Product Characteristics

Color	blue	Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

#### Packaging

Marketing Start Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-8004-45	177 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	10/04/2023	

## Part 2 of 2

### COLD AND FLU NIGHTTIME

acetaminophen, dextromethorphan hbr, triprolidine hcl solution

## Product Information

Item Code (Source)	NDC:0363-8063
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 20 mL
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 20 mL
<b>TRIPROLIDINE HYDROCHLORIDE</b> (UNII: YAN7R5L890) (TRIPROLIDINE - UNII:2L8T9S52QM)	TRIPROLIDINE HYDROCHLORIDE	2.5 mg in 20 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>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

## Product Characteristics

Color	blue	Score	
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<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	FRUIT	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-8063-45	177 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	10/23/2023	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	10/23/2023	

**Labeler** - Walgreen Company (008965063)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	manufacture(0363-4063) , pack(0363-4063)

Revised: 10/2023

Walgreen Company