SEVERE CONGESTION AND COUGH, COLD AND FLU NIGHTTIMEacetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl, triprolidine hcl Walgreen Company

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Walgreens 44-004063-45

### Severe Congestion & Cough

### 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

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

- diabetes
- 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 1 week, 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
- use by expiration date on package
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

# 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

## Nighttime Cold & Flu

# 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:
  - runny nose
  - headache
  - cough
  - sneezing
  - sore throat
  - minor aches and pains
  - itching of the nose or throat
  - 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.

# 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
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- liver disease
- glaucoma
- a breathing problem such as emphysema or chronic bronchitis

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

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

## 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
- 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,

**Principal Display Panel** 

NDC 0363-4063-45

**DAY & NIGHT PACK** 

Walgreens

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PHARMACIST RECOMMENDED<sup>†</sup>

Compare to the active ingredients in MAXIMUM STRENGTH MUCINEX FAST-MAX® Severe Congestion & Cough & NIGHTSHIFT® Cold & Flu<sup>††</sup>

#### Severe

Congestion & Cough DEXTROMETHORPHAN HBr / COUGH SUPPRESSANT GUAIFENESIN / EXPECTORANT PHENYLEPHRINE HCI / NASAL DECONGESTANT

Maximum Strength

- Controls cough
- Relieves nasal & chest congestion
- Thins & loosens mucus
- 12 years & older

NIGHTTIME
Cold & Flu
ACETAMINOPHEN /
PAIN RELIEVER / FEVER REDUCER

DEXTROMETHORPHAN HBr / COUGH SUPPRESSANT

TRIPROLIDINE HCI / ANTIHISTAMINE

Multi-Symptom

- Relieves cough, fever, sore throat, runny nose & sneezing
- 12 years & older

## 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

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

50844 REV0724A00406345

<sup>†</sup>Our pharmacists recommend the Walgreens brand. We invite you to compare to national brands.

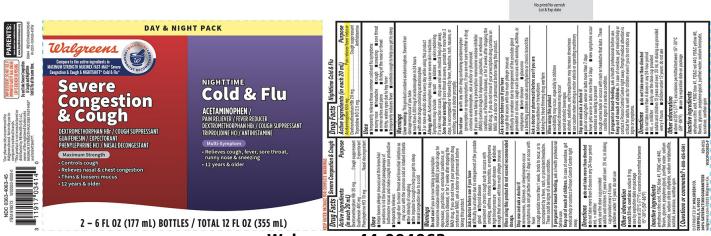
††This product is not manufactured or distributed by RB Health (US) LLC, owner of the registered trademarks MAXIMUM STRENGTH MUCINEX FAST-MAX® and NIGHTSHIFT®.

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**DEERFIELD, IL 60015** 

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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 Product Type HUMAN OTC DRUG Item Code (Source) NDC:0363-4063

|   | Packaging      |   |                         |                       |  |
|---|----------------|---|-------------------------|-----------------------|--|
| 7 | # Item Code    | Package Description                               | Marketing Start<br>Date | Marketing End<br>Date |  |
|   | NDC:0363-4063- | 1 in 1 PACKAGE; Type 0: Not a Combination Product | 10/23/2023              |                       |  |

| Quant  | 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  | <b>Basis of Strength</b>         | Strength           |
| <b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN<br>HYDROBROMIDE | 20 mg<br>in 20 mL  |
| GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)                               | GUAIFENESIN                      | 400 mg<br>in 20 mL |
| PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)            | PHENYLEPHRINE<br>HYDROCHLORIDE   | 10 mg<br>in 20 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)                    |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)            |          |
| WATER (UNII: 059QF0KO0R)                       |          |
| SODIUM BENZOATE (UNII: OJ245FE5EU)             |          |
| TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K) |          |
| SODIUM METABISULFITE (UNII: 4VON5FNS3C)        |          |
| SORBITOL (UNII: 506T60A25R)                    |          |
| SUCRALOSE (UNII: 96K6UQ3ZD4)                   |          |
| XANTHAN GUM (UNII: TTV12P4NEE)                 |          |

| Product Characteristics |       |              |  |
|-------------------------|-------|--------------|--|
| Color                   | blue  | Score        |  |
| Shape                   |       | Size         |  |
| Flavor                  | BERRY | Imprint Code |  |
| Contains                |       |              |  |

| P | Packaging            |  |                         |                       |  |
|---|----------------------|--|-------------------------|-----------------------|--|
| # | Item Code            | Package Description  | Marketing Start<br>Date | Marketing End<br>Date |  |
| 1 | NDC:0363-<br>8004-45 | 177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product |                         |                       |  |

| Marketing In | formation                       |                 |               |
|--------------|---------------------------------|-----------------|---------------|
| Marketing    | Application Number or Monograph | Marketing Start | Marketing End |

| Category           | Citation | Date       | Date |
|--------------------|----------|------------|------|
| OTC Monograph Drug | M012     | 10/04/2023 |      |

# Part 2 of 2

# **COLD AND FLU NIGHTTIME**

acetaminophen, dextromethorphan hbr, triprolidine hcl solution

| i rodact iiii oi iiiatioii | <b>Product</b> | Inform | ation |
|----------------------------|----------------|--------|-------|
|----------------------------|----------------|--------|-------|

Item Code (Source) NDC:0363-8063

**Route of Administration** ORAL

| Active Ingredient/Active Moiety  |                                  |                    |
|--|----------------------------------|--------------------|
| Ingredient Name  | Basis of Strength                | Strength           |
| ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)                           | ACETAMINOPHEN                    | 650 mg<br>in 20 mL |
| <b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN<br>HYDROBROMIDE | 20 mg<br>in 20 mL  |
| TRIPROLIDINE HYDROCHLORIDE (UNII: YAN7R5L890) (TRIPROLIDINE - UNII: 2L8T9S52QM)              | TRIPROLIDINE<br>HYDROCHLORIDE    | 2.5 mg<br>in 20 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)       |          |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8)     |          |
| GLYCERIN (UNII: PDC6A3C0OX)              |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)      |          |
| WATER (UNII: 059QF0KO0R)                 |          |
| SODIUM BENZOATE (UNII: OJ245FE5EU)       |          |
| SUCRALOSE (UNII: 96K6UQ3ZD4)             |          |
| XANTHAN GUM (UNII: TTV12P4NEE)           |          |

| Product Characteristics |       |              |
|-------------------------|-------|--------------|
| Color                   | blue  | Score        |
| Shape                   |       | Size         |
| Flavor                  | FRUIT | Imprint Code |
| Contains                |       |              |

| Packaging   |                     |                 |               |
|-------------|---------------------|-----------------|---------------|
| # Itam Cada | Packago Description | Marketing Start | Marketing End |

| # | item Code            | Раскаде резсприон  | Date | Date |
|---|----------------------|--|------|------|
| 1 | NDC:0363-<br>8063-45 | 177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product |      |      |

| Marketing Information |   |                         |                       |  |
|-----------------------|---|-------------------------|-----------------------|--|
| Marketing<br>Category | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |  |
| OTC Monograph Drug    | M012  | 10/23/2023              |                       |  |

| Marketing Information |   |                         |                       |  |
|-----------------------|---|-------------------------|-----------------------|--|
| Marketing<br>Category | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>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: 12/2025 Walgreen Company