**COLD AND FLU RELIEF SEVERE DAYTIME- acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl tablet, film coated**
**Rite Aid Corporation**

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**Rite Aid 44-640**

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

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

### *Purpose*

Pain reliever/fever reducer
Cough suppressant
Expectorant
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 due to minor throat and bronchial irritation
- 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

### *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
- thyroid disease
- diabetes
- heart disease
- high blood pressure
- 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

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

taking the blood thinning drug warfarin.

**When using this product**

**do not exceed recommended dosage.**

**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*

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

### *Questions or comments?*

**1-800-426-9391**

### *Principal Display Panel*

11822-0640-8

Compare to the active
ingredients in **Vicks®**
**DayQuil® VapoCOOL®**
**SEVERE COLD & FLU**
**+ CONGESTION***

**MAXIMUM STRENGTH**

**SEVERE**
**COLD & FLU** RELIEF

DAY

**ACETAMINOPHEN**
PAIN RELIEVER / FEVER REDUCER

**DEXTROMETHORPHAN HBr**
COUGH SUPPRESSANT
**GUAIFENESIN • PHENYLEPHRINE HCl**
EXPECTORANT • NASAL DECONGESTANT

Temporarily relieves headache, fever,
sore throat, minor aches & pains, nasal/sinus
congestion & sinus pressure,
cough, chest congestion

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® DayQuil® VapoCOOL® SEVERE COLD & FLU + CONGESTION.

50844 REV0722C64008

**DISTRIBUTED BY:** RITE AID,
200 NEWBERRY COMMONS
ETTERS, PA 17319
**www.riteaid.com**

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

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

NDC 11822-0640-8

MAXIMUM STRENGTH

# SEVERE COLD & FLU RELIEF

DAY

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PAIN RELIEVER / FEVER REDUCER
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0 11822 65564 4

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no print / no varnish area
lot no.& exp. dated

PARENTS:
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## Drug Facts

| Active ingredients (in each caplet) | Purpose |
|---|---|
| Acetaminophen 325 mg | Pain reliever/fever reducer |
| Dextromethorphan HBr 10 mg | Cough suppressant |
| Guaifenesin 200 mg | Expectorant |
| Phenylephrine HCl 5 mg | Nasal decongestant |

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

## Drug Facts (continued)

**Uses**
- temporarily relieves common cold and flu symptoms:
- minor aches and pains
- sinus congestion and pressure
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- cough due to minor throat and bronchial irritation
- reduces swelling of nasal passages
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## Drug Facts (continued)

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

**Warnings**

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take
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**Ask a doctor before use if you have**
- liver disease
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- difficulty in urination due to enlargement of the prostate gland

## Drug Facts (continued)

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## Drug Facts (continued)

**Inactive ingredients** 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

**Questions or comments?** 1-800-426-9391

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B-1702-640-08-R3
REV0722C64008

no print / no varnish area

no print / no varnish area

# COLD AND FLU RELIEF SEVERE DAYTIME

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

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:11822-0640 |
| **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) | |
| **CROSPOVIDONE, UNSPECIFIED** (UNII: 2S7830E561) | |
| **FD&C RED NO. 40 ALUMINUM LAKE** (UNII: 6T47AS764T) | |
| **FD&C YELLOW NO. 6 ALUMINUM LAKE** (UNII: GYP6Z2JR6Q) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **MALTODEXTRIN** (UNII: 7CVR7L4A2D) | |
| **MICROCRYSTALLINE CELLULOSE** (UNII: OP1R32D61U) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **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** | NDC:11822-0640-8 | 2 in 1 CARTON | 11/25/2019 | |
| **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 | 11/25/2019 | |

## Labeler - Rite Aid Corporation (014578892)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| LNK International, Inc. | | 832867837 | manufacture(11822-0640) , pack(11822-0640) |

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| LNK International, Inc. | | 832867894 | manufacture(11822-0640) |

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| LNK International, Inc. | | 117025878 | manufacture(11822-0640) |

Revised: 5/2024 Rite Aid Corporation