

**SEVERE COLD AND FLU RELIEF- acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl tablet, film coated
CVS PHARMACY**

CVS 44-503A-SCFH

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 these common cold and flu symptoms:
 - headache
 - cough
 - nasal congestion
 - sore throat
 - minor aches and pains
- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive
- temporarily reduces fever

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:

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

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

- new symptoms occur
- 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
- 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**
- adults and children 12 years and over
 - take 2 caplets every 4 hours
 - swallow whole - do not crush, chew, or dissolve
 - do not take more than 10 caplets in 24 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, D&C yellow #10 aluminum lake, flavor, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, sucralose, talc, titanium dioxide

Questions or comments?

1-800-426-9391

Principal Display Panel

♥CVSHealth®

Compare to the active ingredients in
Tylenol® COLD + FLU SEVERE*

Daytime

Non-Drowsy

Severe Cold & Flu Relief

ACETAMINOPHEN - Pain reliever/Fever reducer

DEXTROMETHORPHAN HBr - Cough suppressant

GUAIFENESIN - Expectorant

PHENYLEPHRINE HCl - Nasal decongestant

Relieves:

Fever, Headache,

Sore throat, Nasal congestion,

Cough, Mucus & Chest congestion

24 CAPLETS

Actual Size

**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 Johnson & Johnson
Corporation, owner of the registered
trademark Tylenol® COLD + FLU
SEVERE.

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One CVS Drive, Woonsocket, RI 02895

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Drug Facts (continued)

■ see end flap for expiration date and lot number
 ■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

Inactive ingredients corn starch, croscopolidone, D&C yellow #10 aluminum lake, flavor, magnesium stearate, mfdocryllane

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Drug Facts (continued)

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■ with other drugs containing acetaminophen

■ 3 or more alcoholic drinks every day while using this product

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

Drug Facts (continued)

Directions ■ do not take more than directed

■ adults and children 12 years and over

■ take 2 caplets every 4 hours

■ swallow whole - do not crush, chew, or dissolve

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■ 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**

Drug Facts (continued)

■ cough that occurs with too much phlegm (mucus)

■ 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 ■ new symptoms occur

■ nervousness, dizziness, or sleepiness occur

■ fever gets worse or lasts more than 3 days

■ pain, nasal congestion, or cough gets worse or lasts more than 7 days

■ cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition. ■ redness or swelling is present

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.

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#970306

01504282973416

CVS Quality
 Made in the USA

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No print/No varnish
 Lot & Exp date

Drug Facts

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Guaifenesin HCl 5 mg Expectorant

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Purpose

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■ minor aches and pains

■ helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive

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CVS Health

Compare to the active ingredients in Tylenol® COLD + FLU SEVERE*
Daytime

Non-Drowsy

Severe Cold & Flu Relief

ACETAMINOPHEN - Pain reliever/Fever reducer
DEXTROMETHORPHAN HBr - Cough suppressant
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Relieves:
 Fever, Headache,
 Sore throat, Nasal congestion,
 Cough, Mucus & Chest congestion

24 CAPLETS

Actual Size

CVS 44-503

SEVERE COLD AND FLU RELIEF
 acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl tablet, film coated

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:69842-503 |
| 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) | |
| CROSPROVIDONE, UNSPECIFIED (UNII: 2S7830E561) | |
| D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| MALTODEXTRIN (UNII: 7CVR7L4A2D) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| 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) | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |
| TALC (UNII: 7SEV7J4R1U) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |

Product Characteristics

| | | | |
|-----------------|---------|---------------------|----------|
| Color | yellow | Score | no score |
| Shape | OVAL | Size | 19mm |
| Flavor | MENTHOL | Imprint Code | 44;503 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|---|-----------------------------|---------------------------|
| 1 | NDC:69842-503-08 | 2 in 1 CARTON | 08/04/2005 | |
| 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 | 08/04/2005 | |

Labeler - CVS PHARMACY (062312574)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|--|
| LNK International, Inc. | | 832867837 | manufacture(69842-503) , pack(69842-503) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|------------------------|
| LNK International, Inc. | | 832867894 | manufacture(69842-503) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|------------------------|
| LNK International, Inc. | | 117025878 | manufacture(69842-503) |

Revised: 6/2025

CVS PHARMACY