

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*

Caplets

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. 50844 REV0922F50308

Distributed by: CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

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CVS Health

Non-Drowsy

Severe Cold & Flu Relief

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Actual Size

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

Daytime

Drug Facts (continued)

Warnings

Severe throat warning: If sore throat is severe, persists for more than 2 days, is accompanied by fever, headache, rash, nausea, or vomiting.

If a skin reaction occurs, stop use and seek medical help right away.

May include: ■ skin redness ■ hives ■ rash

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin redness ■ hives ■ rash

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

■ with other drugs containing acetaminophen

■ more than 4,000 mg of acetaminophen in 24 hours

occur if you take

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

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

Other information

■ each caplet contains: sodium 3 mg

TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN

■ children under 12 years: ask a doctor

■ do not take more than 10 caplets in 24 hours

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

■ take 2 caplets every 4 hours

■ adults and children 12 years and over

Directions ■ do not take more than directed

or symptoms.

critical for adults as well as for children even if you do not notice any signs

contact a Poison Control Center right away. Prompt medical attention is

Keep out of reach of children. In case of overdose, get medical help or

If pregnant or breast-feeding, ask a health professional before use.

be signs of a serious condition. ■ redness or swelling is present

■ fever gets worse or lasts more than 3 days

■ cough comes back or occurs with rash or headache that lasts. These could

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

■ nervousness, dizziness, or sleeplessness occur

■ new symptoms occur

Stop use and ask a doctor if

When using this product do not exceed recommended dosage.

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.

Drug Facts (continued)

■ cough that occurs with too much phlegm (mucus)

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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

Drug Facts (continued)

Active ingredients (in each caplet)

Acetaminophen 325 mg ■ Pain reliever/Fever reducer

Dextromethorphan HBr 10 mg ■ Cough suppressant

Guaifenesin 200 mg ■ Expectorant

Phenylephrine HCl 5 mg ■ Nasal decongestant

Purpose

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Inactive ingredients corn starch, croscopolldone, 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

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)				
CROSPVIDONE, 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: 6/2024

CVS PHARMACY