

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

CVS 44-617 CFS Delisted

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:
 - nasal congestion
 - sore throat
 - headache
 - cough
 - minor aches and pains
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and 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:

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

- 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 accidental 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 12 caplets in any 24-hour period
- adults and children 12 years and over: take 2 caplets every 4 hours
- children under 12 years: do not use

Other information

- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- 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, crospovidone, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, talc, titanium dioxide

Questions or comments?

1-800-426-9391

Principal display panel

**CVS
Health®**

Compare to the active ingredients
in Maximum Strength Mucinex®
FAST-MAX® Cold, Flu & Sore Throat*

**MAXIMUM STRENGTH
Cold, Flu &
Sore Throat**

ACETAMINOPHEN
Pain reliever/Fever reducer

DEXTROMETHORPHAN HBr
Cough suppressant

GUAIFENESIN
Expectorant

PHENYLEPHRINE HCl
Nasal decongestant

Multi-Symptom

- Relieves aches, fever & sore throat
- Controls cough
- Relieves nasal & chest congestion
- Thins & loosens mucus

20 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 Reckitt Benckiser LLC, owner of the registered trademark Maximum Strength Mucinex® FAST-MAX® Cold, Flu & Sore Throat. 50844 ORG091861709

Distributed by: CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

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V-19849

CVS® Quality

Money Back Guarantee



Compare to the active ingredients in Maximum Strength Mucinex® FAST-MAX® Cold, Flu & Sore Throat*

MAXIMUM STRENGTH Cold, Flu & Sore Throat

ACETAMINOPHEN
Pain reliever/Fever reducer

DEXTROMETHORPHAN HBr
Cough suppressant

GUAIFENESIN
Expectorant

PHENYLEPHRINE HCl
Nasal decongestant

Multi-Symptom

- Relieves aches, fever & sore throat
- Controls cough
- Relieves nasal & chest congestion
- Thins & loosens mucus



Actual Size

20 CAPLETS

No print/No varnish
Lot & Exp date

Pectin Benckes LLC, owner of the registered trademark Maximum Strength Mucinex® FAST-MAX®
Cold, Flu & Sore Throat, 50844 086091861709
TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

B-0231-617-09-CFS
086091861709

Drug Facts (continued)

Uses ■ temporarily relieves these common cold and flu symptoms:
 ■ nasal congestion ■ sore throat ■ headache ■ cough
 ■ minor aches and pains ■ helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive ■ temporarily reduces fever

Drug Facts (continued)

■ persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
 ■ 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
 ■ 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 accidental 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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 ■ see and tip for expiration date and lot number

Drug Facts (continued)

alcohol, propylene glycol, sodium starch glycolate, stearic acid, talc, titanium dioxide

Questions or comments? 1-800-426-9891

CVS Health 44-617

COLD, FLU, AND SORE THROAT			
acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl tablet, film coated			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-431
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)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
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)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	red	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	44;617
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-431-09	2 in 1 CARTON	05/02/2020	12/06/2024
1		10 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	05/02/2020	12/06/2024

Labeler - CVS PHARMACY (062312574)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(69842-431) , pack(69842-431)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(69842-431)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(69842-431)

Revised: 11/2023

CVS PHARMACY