

**CONGESTION AND HEADACHE- acetaminophen, guaifenesin, phenylephrine
hcl tablet, film coated
CVS PHARMACY**

CVS 44-615

Active ingredients (in each caplet)

Acetaminophen 325 mg
Guaifenesin 200 mg
Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer
Expectorant
Nasal decongestant

Uses

- temporarily relieves these common cold and flu symptoms:
 - nasal congestion
 - fever
 - headache
 - minor aches and pains
 - sinus congestion and pressure
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily promotes nasal and/or sinus drainage

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.

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
- high blood pressure
- 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
- 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
- fever gets worse or lasts more than 3 days
- pain, nasal congestion, or cough gets worse or lasts more than 7 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**
- 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, 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 active ingredients in Mucinex® FAST-MAX® Congestion & Headache*

MAXIMUM STRENGTH

Congestion & Headache

ACETAMINOPHEN

Pain reliever/Fever reducer

GUAIFENESIN

Expectorant

PHENYLEPHRINE HCl

Nasal decongestant

Multi-Symptom

- Relieves headache & fever
- Relieves nasal & chest congestion
- Thins & loosens mucus

Actual Size

30 CAPLETS

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

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CVS Health. Compare to the active ingredients in Mucinex® FAST-MAX® Congestion & Headache*

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Congestion & Headache


ACETAMINOPHEN
Pain reliever/Fever reducer

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30 CAPLETS

Drug Facts (continued)

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Drug Facts (continued)

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Drug Facts (continued)

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KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

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Guaifenesin 200 mg Expectorant

Phenylephrine HCl 5 mg Nasal decongestant

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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 ■ high blood pressure ■ 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
 ■ cough that occurs with too much phlegm (mucus)
Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.

Drug Facts (continued)

Inactive ingredients corn starch, croscopolone, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, magnesium stearate, methylcellulose, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, talc, titanium dioxide

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CVS 44-615

CONGESTION AND HEADACHE

acetaminophen, guaifenesin, phenylephrine hcl tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-651
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 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)	
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	orange	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	44;615
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-651-01	3 in 1 CARTON	10/14/2020	
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	06/30/2013	

Labeler - CVS PHARMACY (062312574)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(69842-651)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(69842-651) , pack(69842-651)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(69842-651)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(69842-651)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(69842-651)

Revised: 9/2023

CVS PHARMACY