DAYTIME SEVERE COLD AND FLU RELIEF MAXIMUM STRENGTH- acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl tablet, film coated
CVS Pharmacy

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

CVS 44-640-delisted

Active ingredients

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 accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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

- **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

CVSHealth™

Compare to the active ingredients in
Vicks® DayQuil® Severe Cold & Flu*

Severe

NDC 69842-640-08

MAXIMUM STRENGTH
Daytime
Severe Cold/Flu Relief
ACETAMINOPHEN - Pain reliever, Fever reducer
DEXTROMETHORPHAN HBr - Cough suppressant
GUAIFENESIN - Expectorant
PHENYLEPHRINE HCI - Nasal decongestant

Relieves:
Headache, Fever, Coughing, Chest & nasal congestion

Non-Drowsy
Alcohol free
Antihistamine free

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 Procter & Gamble, owner of the registered

trademark Vicks® DayQuil® Severe Cold & Flu.
50844 ORG041764008

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Money Back Guarantee

CVS Health

MAXIMUM STRENGTH

Daytime

Severe Cold/Flu Relief

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Severe

NDC 69842-640-08

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Drug Facts

Active ingredients (in each caplet)	Purpose
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
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Drug Facts (continued)

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- difficulty in urination due to enlargement of the prostate gland

Drug Facts (continued)

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Drug Facts (continued)

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Questions or comments? 1-800-426-9391

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

No print/No varnish
Lot & Exp date

0 50428 40722 4

#954405

B-0231-640-08-H
ORG04176400B

CVS Health

MAXIMUM STRENGTH
Daytime
Severe Cold/Flu Relief

Severe

DAYTIME SEVERE COLD AND FLU RELIEF MAXIMUM STRENGTH

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

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69842-640
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 (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)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	

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:69842-640-08	2 in 1 CARTON	02/27/2014	02/10/2023
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 FINAL	part341	02/27/2014	02/10/2023

Labeler - CVS Pharmacy (062312574)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(69842-640)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(69842-640)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(69842-640)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(69842-640)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(69842-640)

Revised: 3/2020 CVS Pharmacy