

**SEVERE COLD, COLD AND FLU MAXIMUM STRENGTH, DAYTIME, NIGHTTIME-
acetaminophen, dextromethorphan hbr, diphenhydramine hcl, guaifenesin, phenylephrine hcl
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 44-617694

Active ingredients (in each caplet) (Daytime Severe Cold)

Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Guaifenesin 200 mg
Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer
Cough suppressant
Expectorant
Nasal decongestant

Active ingredients (in each caplet) (Nighttime Cold & Flu)

Acetaminophen 325 mg
Diphenhydramine HCl 12.5 mg
Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer
Antihistamine/cough suppressant
Nasal decongestant

Uses

- temporarily relieves these common cold and flu symptoms:
 - headache
 - minor aches and pains
 - nasal congestion
 - cough
 - sore throat
 - runny nose and sneezing (***Nighttime only***)
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive (***Daytime only***)
- controls cough to help you get to sleep (***Nighttime only***)
- temporarily reduces fever

Warnings

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

- with other drugs containing acetaminophen
- more than 4,000 mg of acetaminophen in 24 hours
- 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
- with any other product containing diphenhydramine, even one used on skin (**Nighttime only**)

Ask a doctor before use if you have

- heart disease
- thyroid disease
- diabetes
- liver 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)
- a breathing problem such as emphysema or chronic bronchitis (**Nighttime only**)
- glaucoma (**Nighttime only**)

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers (**Nighttime only**)

When using this product

- **do not exceed recommended dosage**
- excitability may occur, especially in children (**Nighttime only**)
- marked drowsiness may occur (**Nighttime only**)
- avoid alcoholic beverages (**Nighttime only**)
- alcohol, sedatives, and tranquilizers may increase drowsiness (**Nighttime only**)
- be careful when driving a motor vehicle or operating machinery (**Nighttime only**)

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.

If taking NIGHTTIME and DAYTIME products, carefully read each section to ensure correct dosing. Do not take DAY & NIGHT at the same time.

Directions

- **do not use 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 (Daytime only)

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

Inactive ingredients (Nighttime only)

corn starch, croscarmellose sodium, crospovidone, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, iron oxide yellow, magnesium stearate, methacrylic acid and ethyl acrylate copolymer, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium bicarbonate, 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® DAY TIME Severe Cold & NIGHT TIME Cold & Flu*

NDC 69842-694-01

MAXIMUM STRENGTH Daytime Severe Cold ACETAMINOPHEN Pain reliever, Fever reducer DEXTROMETHORPHAN HBr Cough suppressant GUAIFENESIN - Expectorant PHENYLEPHRINE HCl Nasal decongestant Multi-Symptom • Relieves aches, fever & sore throat • Relieves nasal & chest congestion • Controls cough • Thins & loosens mucus For Ages 12 & Over Actual Size	MAXIMUM STRENGTH Nighttime Cold & Flu ACETAMINOPHEN Pain reliever, Fever reducer DIPHENHYDRAMINE HCl Antihistamine, Cough suppressant PHENYLEPHRINE HCl Nasal decongestant Multi-Symptom • Relieves aches, fever • Controls cough • Relieves nasal congestion • Relieves runny nose & sneezing For Ages 12 & Over Actual Size
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20 DAYTIME CAPLETS & 10 NIGHTTIME CAPLETS
TOTAL 30 CAPLETS

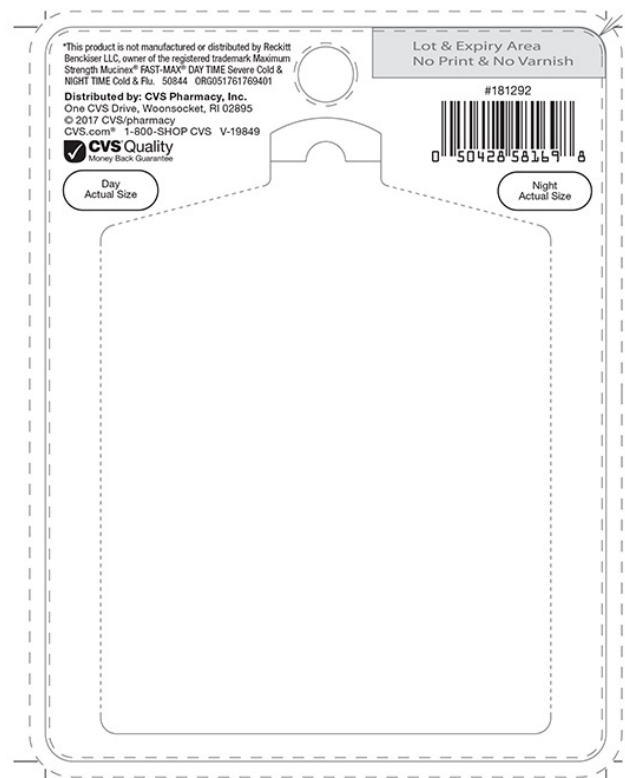
**TAMPER EVIDENT: DO NOT USE IF PACKAGE IS
OPENED OR IF BLISTER UNIT IS TORN, BROKEN
OR SHOWS ANY SIGNS OF TAMPERING**

*This product is not manufactured or distributed by Reckitt Benckiser LLC, owner of the registered trademark Maximum Strength Mucinex® FAST-MAX® DAY TIME Severe Cold & NIGHT TIME Cold & Flu.

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<p>Drug Facts KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION</p> <p>Active ingredients (in each caplet) (Daytime Severe Cold)</p> <table border="1"> <tr> <th>Active ingredients (in each caplet) (Nighttime Cold & Flu)</th> <th>Purpose</th> </tr> <tr> <td>Acetaminophen 325 mg</td> <td>Pain reliever/fever reducer</td> </tr> <tr> <td>Dextromethorphan HBr 10 mg</td> <td>Cough suppressant</td> </tr> <tr> <td>Guaifenesin 200 mg</td> <td>Expectorant</td> </tr> <tr> <td>Phenylephrine HCl 5 mg</td> <td>Nasal decongestant</td> </tr> </table> <p>Uses</p> <ul style="list-style-type: none"> temporarily relieves these common cold and flu symptoms: <ul style="list-style-type: none"> headache minor aches and pains nasal congestion cough sore throat runny nose and sneezing (Nighttime only) helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive (Daytime only) controls cough to help you get to sleep (Nighttime only) temporarily reduces fever <p>Warnings</p> <p>Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take</p> <ul style="list-style-type: none"> with other drugs containing acetaminophen more than 4,000 mg of acetaminophen in 24 hours 3 or more alcoholic drinks every day while using this product <p>PEEL CORNER TO READ COMPLETE DRUG FACTS</p>	Active ingredients (in each caplet) (Nighttime Cold & Flu)	Purpose	Acetaminophen 325 mg	Pain reliever/fever reducer	Dextromethorphan HBr 10 mg	Cough suppressant	Guaifenesin 200 mg	Expectorant	Phenylephrine HCl 5 mg	Nasal decongestant	<p>Drug Facts (continued)</p> <p>Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: <ul style="list-style-type: none"> blisters rash skin reddening If a skin reaction occurs, stop use and seek medical help right away. </p> <p>See 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.</p> <p>Do not use</p> <ul style="list-style-type: none"> 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 with any other product containing diphenhydramine, even one used on skin (Nighttime only) <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> heart disease thyroid disease diabetes liver 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) a breathing problem such as emphysema or chronic bronchitis (Nighttime only) glaucoma (Nighttime only) 	<p>Drug Facts (continued)</p> <p>Ask a doctor or pharmacist before use if you are</p> <ul style="list-style-type: none"> taking the blood thinning drug warfarin taking sedatives or tranquilizers (Nighttime only) <p>When using this product</p> <ul style="list-style-type: none"> do not exceed recommended dosage excitability may occur, especially in children (Nighttime only) marked drowsiness may occur (Nighttime only) avoid alcoholic beverages (Nighttime only) alcohol, sedatives, and tranquilizers may increase drowsiness (Nighttime only) be careful when driving a motor vehicle or operating machinery (Nighttime only) <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> irritation, 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. <p>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.</p> <p>If taking NIGHTTIME and DAYTIME products, carefully read each section to ensure correct dosing. Do not take DAY & NIGHT at the same time.</p>	<p>Drug Facts (continued)</p> <p>Directions</p> <ul style="list-style-type: none"> do not use 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 <p>Other information</p> <ul style="list-style-type: none"> 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 <p>Inactive ingredients (Daytime only) corn starch, croscopollose, 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</p> <p>Inactive ingredients (Nighttime only) corn starch, croscopollose, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, iron oxide yellow, magnesium stearate, methacrylic acid and ethyl acrylate copolymer, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium bicarbonate, stearic acid, talc, titanium dioxide</p> <p>Questions or comments? 1-800-426-8391</p> <p>50844 ORG051761769401 R-0231-617694-01-DF</p>
Active ingredients (in each caplet) (Nighttime Cold & Flu)	Purpose												
Acetaminophen 325 mg	Pain reliever/fever reducer												
Dextromethorphan HBr 10 mg	Cough suppressant												
Guaifenesin 200 mg	Expectorant												
Phenylephrine HCl 5 mg	Nasal decongestant												

CVS Health 44-617694

SEVERE COLD, COLD AND FLU MAXIMUM STRENGTH, DAYTIME, NIGHTTIME

acetaminophen, dextromethorphan hbr, diphenhydramine hcl, guaifenesin, phenylephrine hcl kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-694
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-694-01	1 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	07/01/2017	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BLISTER PACK	10
Part 2	1 BLISTER PACK	10

Part 1 of 2

SEVERE COLD MAXIMUM STRENGTH, DAYTIME

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

Product Information

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 (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)	
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 RED Score no score

Shape	OVAL	Size	19mm
Flavor		Imprint Code	44;6 17
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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 FINAL	part341	04/07/2013	

Part 2 of 2

COLD AND FLU MAXIMUM STRENGTH, NIGHTTIME

acetaminophen, diphenhydramine hcl, phenylephrine hcl tablet, film coated

Product Information

Route of Administration	ORAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	12.5 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPVIDONE (UNII: 2S7830E561)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	

STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	

Product Characteristics

Color	BLUE	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	44;694
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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 FINAL	part341	07/01/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	07/01/2017	

Labeler - CVS Pharmacy (062312574)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(69842-694)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(69842-694)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(69842-694)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(69842-694)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(69842-694)

Revised: 10/2019

CVS Pharmacy