SEVERE COLD, COLD AND FLU MAXIMUM STRENGTH, DAYTIME, NIGHTIME- acetaminophen, dextromethorphan hbr, diphenhydramine hcl, guaifenesin, phenylephrine hcl
CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED

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-Delisted

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

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

Purpose (Daytime Severe Cold)

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 (Nighttime Cold & Flu)

Pain reliever/fever reducer
Antihistamine/cough suppressant
Nasal decongestant

Uses

- temporarily relieves these common cold and flu symptoms:
  - headache
  - nasal congestion
  - cough
  - minor aches and pains
  - 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)***
- temporarily reduces fever
- controls cough to help you get to sleep

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
- 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)***
- use caution 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
- new symptoms occur
- 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 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.

Do not take DAYTIME and NIGHTTIME products at the same time.

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 (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®

DAY & NIGHT COMBO PACK

MAXIMUM STRENGTH **Daytime** **Severe Cold** **Acetaminophen** Pain reliever/Fever reducer Dextromethorphan HBr Cough suppressant Guaifenesin, Expectorant Phenylephrine HCl Nasal decongestant MULTI-SYMPTOM Headache + Body Pain Fever + Sore Throat Cough + Chest Congestion Nasal Congestion For Ages 12+ Actual Size **20** DAYTIME CAPLETS	MAXIMUM STRENGTH **Nighttime** **Cold & Flu** **Acetaminophen** Pain reliever/Fever reducer Diphenhydramine HCl Antihistamine Cough suppressant Phenylephrine HCl Nasal decongestant MULTI-SYMPTOM Headache + Body Pain Fever + Sore Throat Nasal Congestion Sneezing & Runny Nose For Ages 12+ Actual Size **10** NIGHTTIME CAPLETS

30 TOTAL CAPLETS

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

PARENTS:

Learn about teen medicine abuse
www.StopMedicineAbuse.org

Do not take the
Daytime and Nighttime
caplets at the same time.

Distributed by: CVS Pharmacy, Inc.
One CVS Drive, Woonsocket, RI 02895

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CVS 44-617694

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

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

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51316-614

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-614-01	1 in 1 CARTON; Type 0: Not a Combination Product	08/16/2022	02/22/2025

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	2 BLISTER PACK	20
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

Item Code (Source)	NDC:51316-917
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: 3WQ0SDW1A)	
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		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	08/16/2022	

Part 2 of 2

COLD AND FLU MAXIMUM STRENGTH, NIGHTTIME

acetaminophen, diphenhydramine hcl, phenylephrine hcl tablet, film coated

Product Information	
Item Code (Source)	NDC:51316-699
Route of Administration	ORAL

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)	
CROSPOVIDONE (UNII: 2S7830E561)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
FD&C BLUE NO. 2--ALUMINUM LAKE (UNII: 4AQJ3LG584)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

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	08/16/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/16/2022	02/22/2025

Labeler - CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED (062312574)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(51316-614) , pack(51316-614)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(51316-614)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(51316-614)