SEVERE CONGESTION, COUGH, COLD AND FLU RELIEF MAXIMUM STRENGTH, NIGHTTIME- acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl, triprolidine hcl
CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED

CVS 44-004063

Active ingredients (in each 20 mL)

Dextromethorphan HBr 20 mg
Guaifenesin 400 mg
Phenylephrine HCl 10 mg

Purpose

Cough suppressant
Expectorant
Nasal decongestant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily relieves:
  - cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
  - the intensity of coughing
  - the impulse to cough to help you get to sleep
  - nasal congestion due to a cold

Warnings

Do not use

- 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.

Ask a doctor before use if you have

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

- cough that occurs with too much phlegm (mucus)

When using this product

do not exceed recommended dosage.

Stop use and ask a doctor if
- nervousness, dizziness, or sleeplessness occur
- symptoms do not get better within 7 days or occur with fever
- cough persists more than 7 days, tends to recur, or is accompanied by a fever, rash, or persistent headache. 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 overdose, get medical help or contact a Poison Control Center right away.

Directions
- **do not take more than directed**
- do not take more than 6 doses in any 24-hour period
- mL = milliliter
- only use the dose cup provided
- adults and children 12 years and over: 20 mL in dosing cup provided every 4 hours
- children under 12 years: do not use

Other information
- **each 20 mL contains:** sodium 9 mg
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- use by expiration date on package

Inactive ingredients

anhydrous citric acid, FD&C blue #1, FD&C red #40, flavors, glycerin, propylene glycol, purified water, sodium benzoate, sodium citrate dihydrate, sodium metabisulfite, sorbitol, sucralose, xanthan gum

Questions or comments?

1-800-426-9391

Active ingredients (in each 20 mL)

Acetaminophen 650 mg

Dextromethorphan HBr 20 mg
Triprolidine HCl 2.5 mg

Purpose

Pain reliever/fever reducer
Cough suppressant
Antihistamine

Uses

- temporarily relieves these common cold and flu symptoms:
  - cough
  - headache
  - runny nose
  - sneezing
  - sore throat
  - itchy, watery eyes due to hay fever
  - itching of the nose or throat
  - minor aches and pains
- 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:

- rash
- blisters
- 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
- cough that occurs with too much phlegm (mucus)
- difficulty in urination due to enlargement of the prostate gland
- a breathing problem such as emphysema or chronic bronchitis
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- liver disease
- glaucoma

Ask a doctor or pharmacist before use if you are
- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin

When using this product
- **do not exceed recommended dosage**
- excitability may occur, especially in children
- avoid alcoholic beverages
- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- use caution when driving a motor vehicle or operating machinery

Stop use and ask a doctor if
- pain 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 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 4 doses in any 24-hour period
- mL = milliliter
- only use the dose cup provided
- adults and children 12 years and over: 20 mL in dosing cup provided every 4 hours
- children under 12 years: do not use

Other information

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- use by expiration date on package

Inactive ingredients

anhydrous citric acid, FD&C blue #1, FD&C red #40, FD&C yellow #6, flavors, glycerin, propylene glycol, purified water, sodium benzoate, sucralose, xanthan gum

Principal display panel

♥CVS Health® Compare to the active ingredients in Mucinex® FAST-MAX® Severe Congestion & Cough* **MAXIMUM STRENGTH** **Severe Congestion** **& Cough Relief** DEXTROMETHORPHAN HBr - Cough suppressant GUAIFENESIN - Expectorant PHENYLEPHRINE HCl - Nasal decongestant Multi-Symptom • Controls cough • Relieves nasal & chest congestion • Thins & loosens mucus For Ages 12 & Over Mixed Berry Flavor	**♥CVS** Health® Compare to the active ingredients in Mucinex® NIGHTSHIFT® Cold & Flu* **Nighttime** **Cold & Flu Relief** **ACETAMINOPHEN** - Pain reliever/Fever reducer DEXTROMETHORPHAN HBr - Cough suppressant TRIPROLIDINE HCl - Antihistamine Multi-Symptom • Relieves cough & sore throat • Reduces fever • Relieves runny nose & sneezing For Ages 12 & Over Mixed Fruit Flavor

TWO - 6 FL OZ (177 mL) BOTTLES / TOTAL 12 FL OZ (355 mL)

TAMPER EVIDENT: DO NOT USE IF IMPRINTED
SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

PARENTS:
Learn about teen medicine abuse
www.StopMedicineAbuse.org

Do not take Severe Congestion & Cough Relief and Cold & Flu Relief at the same time.

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SEVERE CONGESTION, COUGH, COLD AND FLU RELIEF MAXIMUM STRENGTH, NIGHTTIME

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51316-463

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-463-99	1 in 1 PACKAGE; Type 0: Not a Combination Product	05/27/2022	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE, PLASTIC	177 mL
Part 2	1 BOTTLE, PLASTIC	177 mL

Part 1 of 2

SEVERE CONGESTION AND COUGH RELIEF MAXIMUM STRENGTH

dextromethorphan hbr, guaifenesin, phenylephrine hcl solution

Product Information

Item Code (Source)	NDC:51316-004
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 20 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 20 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 20 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	blue	**Score**	
Shape		**Size**	
Flavor	BERRY (MIXED)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-004-45	177 mL in 1 BOTTLE, PLASTIC; 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	05/27/2022	

Part 2 of 2

COLD AND FLU RELIEF NIGHTTIME

acetaminophen, dextromethorphan hbr, triprolidine hcl solution

Product Information

Item Code (Source)	NDC:51316-063
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 20 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 20 mL
TRIPROLIDINE HYDROCHLORIDE (UNII: YAN7R5L890) (TRIPROLIDINE - UNII:2L8T9S52QM)	TRIPROLIDINE HYDROCHLORIDE	2.5 mg in 20 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	blue	**Score**	
Shape		**Size**	
Flavor	FRUIT (MIXED)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-063-45	177 mL in 1 BOTTLE, PLASTIC; 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	05/27/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	05/27/2022	

Labeler - CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED (062312574)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	manufacture(51316-463) , pack(51316-463)

Revised: 10/2023 CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED