DAYTIME MUCUS RELIEF SEVERE CONGESTION AND COUGH AND NIGHTTIME COLD AND FLU MAXIMUM STRENGTH- dextromethorphan hbr, guaifenesin, phenylephrine hcl, acetaminophen, diphenhydramine hcl, 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.

Drug Facts

Active ingredients for Day Time (in each 20 mL)

Dextromethorphan HBr 20 mg

Guaifenesin 400 mg

Phenylephrine HCl 10 mg

Active ingredients for Night Time (in each 20 mL)

Acetaminophen 650 mg

Diphenhydramine HCl 25 mg

Phenylephrine HCl 10 mg

Purposes for Day Time

Cough suppressant

Expectorant

Nasal decongestant

Purpose for Night Time

Pain reliever/fever reducer

Antihistamine/Cough suppressant

Nasal decongestant

Uses

Daytime

- 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 irritant
  - the intensity of coughing
  - the impulse to cough to help you get to sleep
  - nasal congestion due to a cold

Nighttime

- temporarily relievesthese common cold and flu symptoms

- cough
- nasal congestion
- minor aches and pains
- sore throat
- headache
- runny nose
- sneezing
- temporarily reduces fever
- controls cough to help you get to sleep

Warnings

Nighttime

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:

- skin reddening
- blisters
- rash.

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

Daytime

- if you are taking a prescription monoamine oxidase inhibitor (MAOI) (certan 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.
- for children under 12 years of age

Nighttime

- With any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- with any other drug containing diphenhydramine, even one used on the skin
- if you are taking a prescription monoamine oxidase inhibitor (MAOI) (certan 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
- for children under 12 years of age

Ask a doctor before use if you have

Daytime
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, emphysema
- cough that occurs with too much phlegm (mucus)

Nighttime
- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis
- 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

Nighttime
- you are taking the blood thinning drug warfain
- you are taking sedatives or tranquilizers

When using this product

Daytime

do not use more than directed.

Nighttime
- do not use more than directed
- excitability may occur, especially in children
- marked drowsinessmay occur
- alcohol, sedative, and tranquilizers may increase drowsiness
- avoid alcohol drinks
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

Daytime
- nervousness, dizziness or sleeplessness occur
- symptoms do not get better within 7 days or occur with fever
- cough comes back, or occurs with fever, rash, or headache that lasts.

These could be signs of a serious condition.

Nighttime
- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, or cough gets worse, or lasts more than 7 days
- fever gets worse, or last more than 3 days
- redness or swelling is present

- new symptoms occur
- cough comes back, or occurs with fever, rash, or headache that lasts.

These could be signs of a serious condition.

If pregnant or breast-feeding,

Daytime

ask a health professional before use

Nighttime

ask a health professional before use

Keep out of reach of children.

Daytime

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Nighttime

Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Quick medical attention is critical for adult as well as for children even if you do not notice any signs or symptoms

Directions

Daytime

- do not take more than 6 doses in any 24-hour period
- measure only with dosing cup provided. Do not use any other dosing device
- keep dosing cup with product
- mL= milliliter
- shake well before using
- adult and children 12 years of age and older: 20 mL in dosing cup provided avery 4 hours
- Children under 12 years of age do not use

Nighttime

- **do not take more than directed (see overdose warning)**
- do not take more than 6 doses in any24-hour period
- measure only with dosing cup provided. Do not use any other dosing device
- keep dosing cup with product
- mL= milliliter
- dose as follows or as directed by a doctor
- adult and children 12 years and older: 20 mL every 4 hours while symptoms last
- children under 12 years of age: do not use

Other information

Daytime

- each 20 mL contains: **sodium 17 mg**
- store at 20-25ºC (68-77ºF). Do not refrigerate.

Nighttime

- each 20 mL contains: sodium 10 mg
- store at 20-25ºC (68-77ºF). Do not refrigerate

Inactive ingredients

Inactive ingredients for Day Time

citric acid, disodium EDTA, FD&C blue #1 FD&C red #40, flavor, glycerin, propyl gallate, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol, sucralose,xanthan gum

Inactive ingredients for Night Time

citric acid, EDTA disodium, FD&C blue #1, Fd&C red #40, flavor, glycerin, propylene gallate, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol, sucralose, xanthan gum

Principal Display Panel

DAYTIME

Severe Cough & Congestion

DEXTROMETHORPHAN HBr - Cough Suppressant

GUAIFENESIN - Expectorant

PHENYLEPHRINE HCI - Nasal Decongestant

MAXIMUM STRENGTH

Multi-Symptom

- Relieves nasal & chest congestion
- Soothes Cough
- Thins & loosen mucus

For ages 12 & over

FL OZ (mL)

Compare to the active ingredients in Maximum Strength Mucinex®FAST-MAX® Severe Congestion & Cough and Nighttime Cold & Flu*

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

*This product is not manufactured or distributed by Reckitt Benckiser, distributor of Maximum Strength Mucinex® FAST-MAX® Severe Congestion & Cough & Nighttime Cold & Flu

NIGHTTIME

Cold & FLU

ACETAMINOPHEN - Pain Reliever ; Fever Reducer

DIPHENHYDRAMINE HCl - Antihistamine / Cough Suppressant

PHENYLEPHRINE HCl / Nasal Decongestant

MAXIMUM STRENGTH

Multi-Strength

- Relieves headache & fever
- Controls cough

- Relieves nasal congestion
- Relieves runny nose & sneezing

For ages 12 & over

FL OZ (mL)

Distributed by: CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

CVS.com

Product Label

CVS HEALTH Severe Cough & Congestion Nighttime Cold & Flu

DAYTIME MUCUS RELIEF SEVERE CONGESTION AND COUGH AND NIGHTTIME COLD AND FLU MAXIMUM STRENGTH

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

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69842-462

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:69842-462-12	1 in 1 KIT; Type 0: Not a Combination Product	04/30/2018	

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

DAYTIME MUCUS RELIEF SEVERE CONGESTION AND COUGH MAXIMUM STRENGTH

dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid

Product Information	
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)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		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 FINAL	part341	04/30/2018	

Part 2 of 2

NIGHTTIME COLD AND FLU MAXIMUM STRENGTH

acetaminophen, diphenhydramine hcl, phenylephrine hcl liquid

Product Information

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
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 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)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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 FINAL	part341	04/30/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	04/30/2018	

Labeler - CVS Pharmacy (062312574)

Revised: 10/2019 CVS Pharmacy