

**SEVERE COLD- acetaminophen, dextromethorphan hbr, guaifenesin,  
phenylephrine hcl solution  
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.*

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**CVS Pharmacy, Inc. Severe Cold Drug Facts**

**Active ingredients (in each 20 mL)**

Acetaminophen 650 mg

Dextromethorphan HBr 20 mg

Guaifenesin 400 mg

Phenylephrine HCl 10 mg

**Purposes**

Pain reliever/fever reducer

Cough suppressant

Expectorant

Nasal decongestant

**Uses**

- temporarily relieves these common cold and flu symptoms:
- cough
- nasal congestion
- minor aches and pains
- sore throat
- headache
- stuffy nose
- sinus congestion and pressure
- temporarily reduces fever
- 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:

- 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**

- 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
- heart disease
- diabetes
- high blood pressure
- thyroid disease
- trouble urinating due to an enlarged prostate gland
- 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 you are**

taking the blood thinning drug warfarin

### **When using this product**

**do not use more than directed**

### **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.**

**Overdose warning:** In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick 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 (see Overdose warning)**
- do not take more than 5 doses in any 24-hour period
- measure only with dosing cup provided
- do not use dosing cup with other products
- dose as follows or as directed by a doctor
- adults and children 12 years of age and older: 20 mL in dosing cup provided every 4 hours
- children under 12 years of age: do not use

**Other information**

- **each 20 mL contains:** sodium 7 mg
- store at 20-25°C (68-77°F)
- do not refrigerate

**Inactive ingredients**

anhydrous citric acid, benzyl alcohol, edetate disodium, FD&C blue #1, FD&C red #40, flavor, glycerin, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol solution, sucralose, triethyl citrate, xanthan gum

**Questions or comments?**

**1-800-719-9260**

**Package/Label Principal Display Panel**

CVS Health™

Compare to the active ingredients in Mucinex® Fast-Max® Severe Cold

## MAXIMUM STRENGTH

Severe Cold

Acetaminophen – Pain reliever, Fever reducer

Dextromethorphan HBr – Cough suppressant

Guaifenesin – Expectorant

Phenylephrine HCl – Nasal decongestant

## MULTI-SYMPTOM

Controls cough

Thins & loosens mucus

Relieves nasal & chest congestion

Relieves aches, fever & sore throat

FOR AGES 12+

6 FL OZ (180 mL)

**CVS Health** Compare to the active ingredients in Mucinex® Fast-Max® Severe Cold\* NDC 69842-823-30

**NO COPY AREA** **NO COPY AREA**

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**6 FL OZ (180 mL)**

: 7W83D 17 F4

**Do not use if printed neckband is broken or missing.**

**PARENTS:**  
 Learn about teen medicine abuse  
[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)

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 Money Back Guarantee

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**Drug Facts**

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**PEEL CORNER TO READ COMPLETE DRUG FACTS AND INFORMATION**

: 7W83D 17 B3

**Drug Facts (continued)**

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**Ask a doctor before use if you have** ■ liver disease ■ heart disease ■ diabetes ■ high blood pressure ■ thyroid disease ■ trouble urinating due to an enlarged prostate gland ■ 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 you are taking the blood thinning drug warfarin**

**When using this product do not use more than directed**

**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.

**Drug Facts (continued)**

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**Other information**  
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 ■ do not refrigerate

**Inactive ingredients** anhydrous citric acid, benzyl alcohol, edetate disodium, FD&C blue #1, FD&C red #40, flavor, glycerin, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol solution, sucralose, triethyl citrate, xanthan gum

**Questions or comments?**  
 1-800-719-9260

\*This product is not manufactured or distributed by Reckitt Benckiser, distributor of Mucinex® Fast-Max® Severe Cold.

**SEVERE COLD**  
 acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl solution

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69842-823
<b>Route of Administration</b>	ORAL		

<b>Active Ingredient/Active Moiety</b>		
<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 20 mL
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 20 mL
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 20 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 20 mL

<b>Inactive Ingredients</b>	
<b>Ingredient Name</b>	<b>Strength</b>
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>EDETATE SODIUM</b> (UNII: MP1J8420LU)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SODIUM CITRATE, UNSPECIFIED FORM</b> (UNII: 1Q73Q2JULR)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>TRIETHYL CITRATE</b> (UNII: 8Z96QXD6UM)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

<b>Product Characteristics</b>			
<b>Color</b>	BLUE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	FRUIT	<b>Imprint Code</b>	
<b>Contains</b>			

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-823-30	180 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/03/2018	

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part341	08/03/2018	

**Labeler** - CVS Pharmacy (062312574)

Revised: 10/2022

CVS Pharmacy