

**SEVERE COUGH COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, guaifenesin solution**  
**CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED**

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**CVS Pharmacy, Inc. Severe Cough Cold & Flu Drug Facts**

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

Acetaminophen 650 mg

Dextromethorphan HBr 20 mg

Guaifenesin 400 mg

**Purposes**

Pain reliever/fever reducer

Cough suppressant

Expectorant

**Uses**

- temporarily relieves these symptoms occurring with a cold or flu:
  - cough due to minor throat and bronchial irritation
  - minor aches and pains
  - sore throat
  - headache
- temporarily reduces fever
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes 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**

- 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.
- 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 have ever had an allergic reaction to this product or any of its ingredients

### **Ask a doctor before use if you have**

- liver disease
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema

### **Ask a doctor or pharmacist before use if you are**

taking the blood thinning drug warfarin

### **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.**

**Overdose warning:** In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). 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 5 doses in any 24-hour period
- do not exceed recommended dosage. Taking more than the recommended dose (overdose) may cause serious liver damage.
- measure only with dosing cup provided
- keep dosing cup with product
- mL = milliliter
- this adult product is not intended for use in children under 12 years of age

age	dose
adults and children 12 years and over	20 mL every 4 hours
children under 12 years	do not use

### Other information

- **each 20 mL contains:** sodium 14 mg
- store at 20-25°C (68-77°F). Do not refrigerate.

### Inactive ingredients

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

### Questions or comments?

**1-800-719-9260**

### Package/Label principal display panel

CVS™

Raspberry Flavor

Maximum Strength†

SEVERE COUGH COLD & FLU

Acetaminophen

Pain Reliever, Fever Reducer

Dextromethorphan HBr

Cough Suppressant

Guaifenesin

Expectorant

Compare to Robitussin® Maximum Strength Severe Multi-Symptom Cough Cold + Flu active ingredients

Relieves: Cough, Sore throat, Body aches, Fever, Chest congestion

For Adults & Children Ages 12 & Over

New Formula

8 FL OZ (237 mL)

†Maximum strength claim based on maximum levels of active ingredients per 4 hour dose.



SEVERE COUGH COLD AND FLU				
acetaminophen, dextromethorphan hydrobromide, guaifenesin solution				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51316-189	
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	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)		GUAIFENESIN	400 mg in 20 mL	
Inactive Ingredients				
Ingredient Name			Strength	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
BENZYL ALCOHOL (UNII: LKG8494WBH)				
EDETATE DISODIUM (UNII: 7FLD91C86K)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
GLYCERIN (UNII: PDC6A3C0OX)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)				
SORBITOL SOLUTION (UNII: 8KW3E207O2)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
XANTHAN GUM (UNII: TTV12P4NEE)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-189-34	1 in 1 CARTON	08/29/2025	
1		237 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:51316-189-26	1 in 1 CARTON	08/29/2025	
2		118 mL in 1 BOTTLE; 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	08/29/2025	

**Labeler -** CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED (062312574)

Revised: 9/2025 CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED