

**SEVERE COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride solution**  
**CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED**

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

**Active ingredients (in each 15 mL)**

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Doxylamine Succinate 6.25 mg

Phenylephrine HCl 5 mg

**Purpose**

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Nasal decongestant

**Uses**

temporarily relieves common cold/flu symptoms:

- nasal congestion
- sinus congestion and pressure
- cough due to minor throat and bronchial irritation
- cough to help you sleep
- minor aches and pains
- headache
- fever
- sore throat
- runny nose and sneezing
- reduces swelling of nasal passages
- temporarily restores freer breathing through the nose
- promotes nasal and/or sinus drainage

**Warnings**

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if

- adult takes more than 4,000 mg of acetaminophen in 24 hours
- child takes more than 5 doses in 24 hours

- taken with other drugs containing acetaminophen
- adult has 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.
- to make a child sleepy
- 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
- glaucoma
- thyroid disease
- diabetes
- high blood pressure
- trouble urinating due to an enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema

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

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

### **When using this product**

- **do not use more than directed**
- excitability may occur, especially in children
- marked drowsiness may occur

- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, and tranquilizers may increase drowsiness

### Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- pain, nasal congestion, or cough gets worse or lasts more than 5 days (children) or 7 days (adults)
- 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

- take only as directed – see Overdose warning
- only use the dose cup provided
- do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over	30 mL every 4 hrs
children 6 to under 12 yrs	15 mL every 4 hrs
children 4 to under 6 yrs	ask a doctor
children under 4 yrs	do not use

### Other information

- **each 15 mL contains:** sodium 15 mg
- store at 20-25°C (68-77°F)

## **Inactive ingredients**

anhydrous citric acid, D&C yellow #10, edetate disodium, FD&C green #3, FD&C red #40, FD&C yellow #6, flavor, glycerin, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium chloride, sodium citrate, sorbitol solution, sucralose, xanthan gum

## **Questions?**

**1-800-719-9260**

## **Package/Label Principal Display Panel**

CVS™

Honey Flavor

Nighttime

SEVERE COLD & FLU

Acetaminophen

Pain Reliever, Fever Reducer

Phenylephrine HCl

Nasal Decongestant

Dextromethorphan HBr

Cough Suppressant

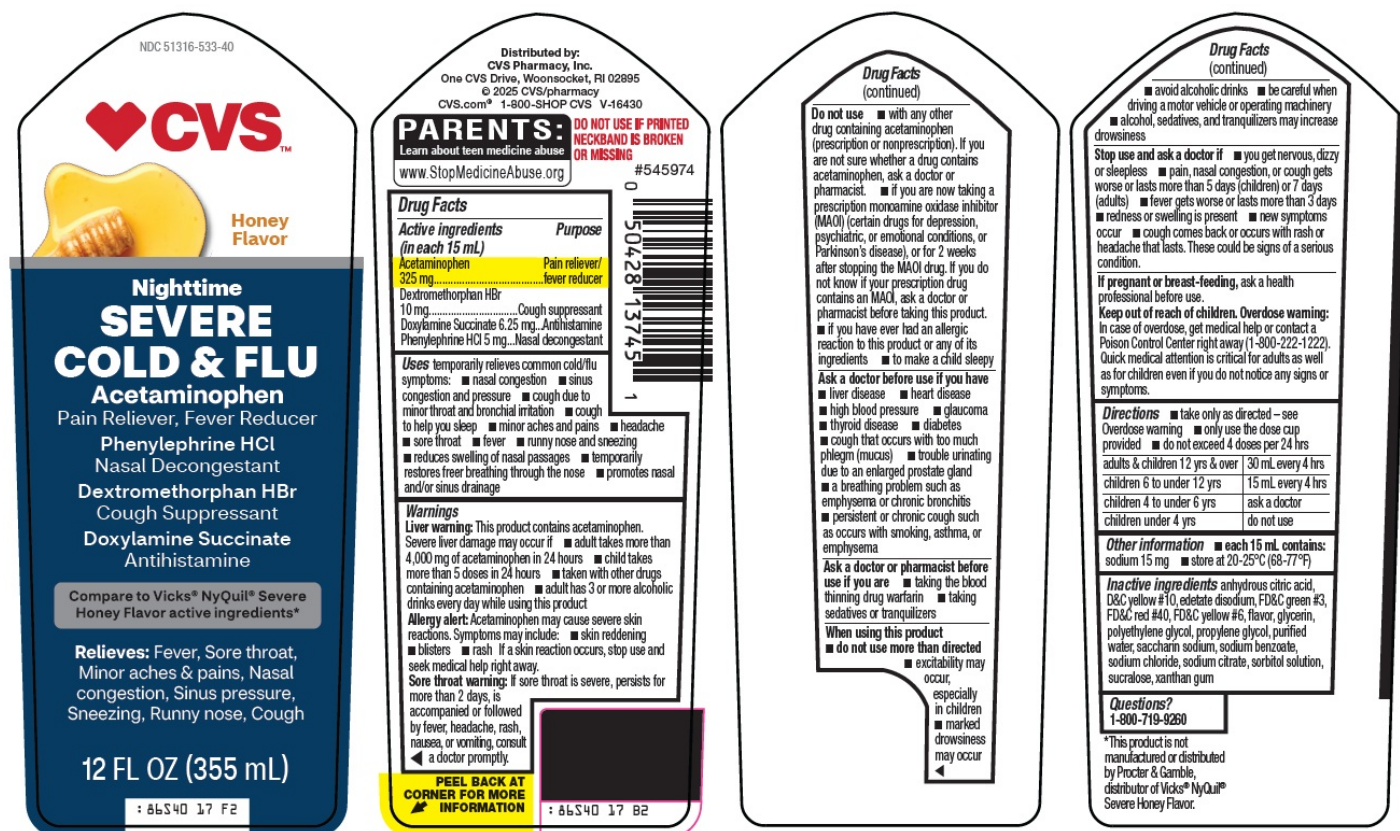
Doxylamine Succinate

Antihistamine

Compare to Vicks® NyQuil® Severe Honey Flavor active ingredients

Relieves: Fever, Sore throat, Minor aches & pains, Nasal congestion, Sinus pressure, Sneezing, Runny nose, Cough

12 FL OZ (355 mL)



## SEVERE COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride solution

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51316-533
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg in 15 mL
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 15 mL
<b>DOXYLAMINE SUCCINATE</b> (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg in 15 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 15 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	

<b>FD&amp;C GREEN NO. 3</b> (UNII: 3P3ONR6O1S)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>SODIUM CITRATE, UNSPECIFIED FORM</b> (UNII: 1Q73Q2JULR)	
<b>SORBITOL SOLUTION</b> (UNII: 8KW3E207O2)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-533-40	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/26/2026	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	01/26/2026	

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

Revised: 1/2026

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