

**SEVERE COLD DAYTIME- acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl capsule**

**CVS Pharmacy**

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**Drug Facts**

**Active ingredients (in each softgels)**

**Acetaminophen 325 mg**

Dextromethorphan HBr 10 mg

Guaifenesin 200 mg

Phenylephrine HCl 5 mg

**Purposes**

**Pain reliever/fever reducer**

Antihistamine/Cough suppressant

Expectorant

Nasal decongestant

**Uses**

- temporarily relieves these common cold and flu symptoms:
  - headache
  - nasal congestion
  - sore throat
  - cough
  - minor ache and pain
- 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.

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

- liver disease
- diabetes
- high blood pressure
- heart disease
- 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**

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 fever, 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:** 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 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 12 softgels in any 24-hour period
- adults and children 12 years and older: take 2 softgels every 4 hours
- children under 12 years of age: do not use

### **Other information**

- store between 15-30°C (59-86°)
- avoid excessive heat
- swallow whole; do not crush, chew, or dissolve

### **Inactive ingredients**

FD&C red 40, FD&C yellow #6, gelatin, glycerin, mannitol\*, polyethylene glycol, povidone, propylene glycol, purified water, sorbitan, sorbitol, titanium dioxide

\*may contain this ingredient

### **Questions or comments?**

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

### **Principal Display Panel**

Compare to active ingredients in Maximum Strength Mucinex® Fast-Max® Severe Cold†  
Severe Cold

ACETAMINOPHEN - Pain reliever, Fever reducer

DEXTROMETHORPHAN HBr - Cough Suppressant

GUAIFENESIN - Expectorant

PHENYLEPHRINE HCl - Nasal decongestant

MAXIMUM STRENGTH

Multi-Symptom

- Relieves aches, fever & sore throat
- Controls cough
- Relieves nasal & chest congestion
- Thins & loosen mucus

For Ages 12 Years & Older

Alcohol Free

SOFTGELS

(\*\*Liquid-filled capsules)

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

**TAMPER EVIDENT: DO NOT USE IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING**

**KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.**

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### Package Label

<b>Drug Facts</b> <b>Active ingredients (in each softgel)</b> Acetaminophen 325 mg..... Pain reliever/fever reducer Dextromethorphan HBr 10 mg..... Cough suppressant Guaifenesin 200 mg..... Expectorant Phenylephrine HCl 5 mg..... Nasal decongestant <b>Purposes</b> temporarily relieves these common cold and flu symptoms headache nasal congestion sore throat cough minor aches and pains helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive temporarily reduces fever <b>Warnings</b> <b>Liver warnings:</b> 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 <b>Allergy alert:</b> 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. <b>Sore throat warning:</b> 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. <b>Do not use</b> 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. <b>Ask a doctor before use if you have</b> liver disease diabetes high blood pressure heart disease thyroid disease trouble urinating due to an enlarged prostate gland a persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema cough that occurs with too much phlegm (mucus)	<b>Drug Facts (continued)</b> <b>Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.</b> <b>When using this product, do not use more than directed.</b> <b>Stop use and ask a doctor if</b> 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. <b>If pregnant or breast-feeding, ask a health professional before use.</b> <b>Keep out of reach of children.</b> <b>Overdose warning:</b> 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 adults as well as for children even if you do not notice any signs or symptoms. <b>Directions</b> do not take more than directed (see Overdose warning) do not take more than 12 softgels in any 24-hour period adults and children 12 years of age and older: take 2 softgels every 4 hours children under 12 years of age: do not use <b>Other information</b> store between 15-30°C (59-86°F) avoid excessive heat swallow whole; do not crush, chew, or dissolve <b>Inactive ingredients</b> FD&C red #40, FD&C yellow #6, gelatin, glycerin, mannitol*, polyethylene glycol, povidone, propylene glycol, purified water, sorbitan, sorbitol, titanium dioxide *may contain this ingredient <b>Questions or comments?</b> Call 1-877-753-3936 Monday-Friday 9AM-5PM EST  *This product is not manufactured or distributed by Reckitt Benckiser, distributor of Maximum Strength Mucinex® Fast-Max® Day Severe Cold. <b>TAMPER EVIDENT: DO NOT USE IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.</b> <b>KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.</b>	 <p>Compare to the active ingredients in Maximum Strength Mucinex® Fast-Max® Day Severe Cold† NDC 69842-837-16</p> <h1>Severe Cold</h1> <p><b>ACETAMINOPHEN</b> - Pain reliever, Fever reducer <b>DEXTROMETHORPHAN HBr</b> - Cough suppressant <b>GUAIFENESIN</b> - Expectorant <b>PHENYLEPHRINE HCl</b> - Nasal decongestant</p> <h2>MAXIMUM STRENGTH</h2> <p><b>Multi-Symptom</b></p> <ul style="list-style-type: none"><li>Relieves aches, fever &amp; sore throat</li><li>Controls cough</li><li>Relieves nasal &amp; chest congestion</li><li>Thins &amp; loosens mucus</li></ul> <p><b>For Ages 12 Years &amp; Older</b> <b>Alcohol Free</b></p>  <p>Actual Size</p> <p><b>16 SOFTGELS**</b> (*Liquid-filled capsules)</p> 
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**CVS HEALTH Maximum Strength Severe Cold**

# SEVERE COLD DAYTIME

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl capsule

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69842-837
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SORBITAN</b> (UNII: 6O92ICV9RU)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	orange	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	341;12A
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-837-16	16 in 1 CARTON	01/30/2019	12/31/2024
1		1 in 1 BLISTER PACK; 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	01/30/2019	12/31/2024

**Labeler** - CVS Pharmacy (062312574)

Revised: 10/2023

CVS Pharmacy