

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

**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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### **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**

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 20-25°C (68-77°F)
- 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

**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 Liquid Gel\*\*

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 +

Alcohol Free

SOFTGELS†

(†Liquid-filled capsules)

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

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

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

Distributed by: CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

CVS.com

# Package Label

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**Active ingredients (in each softgel)**

Acetaminophen 325 mg.....Pain reliever/fever reducer  
 Dextromethorphan HBr 10 mg.....Cough suppressant  
 Guaifenesin 200 mg.....Expectorant  
 Phenylephrine HCl 5 mg.....Nasal decongestant

**Uses**

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  - sore throat
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  - minor aches and pains
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- 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)

**Drug Facts (continued)**

**Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.**

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**Questions or comments?**  
 Call 1-877-753-3835 Monday-Friday 9AM-5PM EST

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

**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.**



**Severe Cold**

**MAXIMUM STRENGTH**

**CVS Health**

Compare to the active ingredients in Maximum Strength Mucinex® Fast-Max® Severe Cold Liquid Gels\*\*  
 NDC 69842-905-16

**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+**  
 Alcohol Free


**16 SOFTGELS<sup>†</sup>** (†Liquid-filled capsules)

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 PLD-0588A FC006558

## 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:69842-505
<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
MANNITOL (UNII: 3OWL53L36A)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
GELATIN (UNII: 2G86QN327L)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

## Product Characteristics

Color	ORANGE	Score	no score
Shape	CAPSULE	Size	20mm
Flavor		Imprint Code	12A
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-505-16	16 in 1 CARTON	12/27/2019	
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 FINAL	part341	12/27/2019	

**Labeler** - CVS Pharmacy (062312574)

Revised: 3/2020

CVS Pharmacy