

**MAXIMUM STRENGTH SEVERE CONGESTION RELIEF- acetaminophen,  
dextromethorphan hydrobromide, guaifenesin, phenylephrine  
hydrochloride capsule, liquid filled  
Spirit Pharmaceuticals LLC**

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**Maximum Strength Severe Congestion Relief**

***Drug Facts***

***Active ingredients (in each caplet)***

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Guaifenesin 200 mg

Phenylephrine HCl 5 mg

***Purpose***

Pain reliever/fever reducer

Cough suppressant

Expectorant

Nasal decongestant

***Uses***

• for the temporary relief of the following cold/flu symptoms: • minor aches and pains • headache • sore throat • nasal congestion • cough • helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive • temporarily reduces fever

***Warnings***

**Liver warning:**

This product contains acetaminophen. The maximum daily dose of this product is 10 caplets (3,250 mg acetaminophen) in 24 hours. 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 • high blood pressure • thyroid disease • diabetes • 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 exceed recommended dosage**

### **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.**

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

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adults and children • take 2 caplets every 4 hours • swallow whole; do not crush, chew  
12 years & over or dissolve • do not take more than 10 caplets in 24 hours  
children under 12



# MAXIMUM STRENGTH SEVERE CONGESTION RELIEF

acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride capsule, liquid filled

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68210-4194
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
<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>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	5 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ05DW1A)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<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>	OVAL	<b>Size</b>	26mm
<b>Flavor</b>		<b>Imprint Code</b>	341
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-4194-1	10 in 1 BLISTER PACK; Type 0: Not a Combination Product	12/28/2021	

## 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 Drug	M012	12/28/2021	

**Labeler** - Spirit Pharmaceuticals LLC (179621011)

Revised: 12/2024

Spirit Pharmaceuticals LLC