

**MULTI-SYMPTOM DAYTIME- acetaminophen, dextromethorphan hydrobromide, and phenylephrine hydrochloride capsule, liquid filled SPIRIT PHARMACEUTICALS LLC**

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**Non-Drowsy DAYTIME COLD & FLU MULTI-SYMPTOM**

***Drug Facts***

***Active ingredients (in each softgel)***

***Purposes***

Acetaminophen 325 mg.....Pain reliever/fever reducer  
Dextromethorphan hydrobromide 10 mg.....Cough suppressant  
Phenylephrine hydrochloride 5 mg.....Nasal decongestant

**Uses**

temporarily relieves common cold/flu symptoms:

- nasal congestion
- cough due to minor throat & bronchial irritation
- sore throat
- headache
- minor aches/pains
- fever

**Warnings**

**Liver warning**

This product contains acetaminophen. Severe liver damage may occur if you take

- more than 10 softgels in 24 hours, which is the maximum daily amount for this product
- 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

**Sore throat warning:**

If sore throat is severe, lasts for more than 2 days, occurs with or is followed by fever, headache, rash, nausea, or vomiting, see 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
- heart disease
- thyroid disease
- diabetes
- high blood pressure
- trouble urinating due to enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough as occurs with smoking, asthma, or emphysema

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

### **When using this product**

- **do not use more than directed.**

### **Stop use and ask a doctor if**

- you get nervous, dizzy, or sleepless
- pain, nasal congestion or cough gets worse or last 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. Quick medical attention is critical for adults and for children, even if you do not notice any signs or symptoms.

### **Directions**

- do not take more than the recommended dose
- adults and children 12 years and over: take 2 softgels with water every 4 hours. Do not exceed 10 softgels in 24 hours or as directed by a doctor.
- children under 12 years: do not use

### **Other information**

- store at room temperature. Avoid excessive heat above 40°C (104°F).

### Inactive ingredients

FD&C Red No. 40, FD&C Yellow No.6. gelatin, glycerin, polyethylene glycol 400, povidone, propylene glycol, purified water, sorbitol sorbitan, titanium dioxide

### Questions or comments?

**1-888-333-9792**

### PRINCIPAL DISPLAY PANEL

Multi-symptom

Non-drowsy Daytime  
Cold & Flu

Acetaminophen - Pain Reliever / Fever Reducer  
Dextromethorphan HBr - Cough Suppressant  
Phenylephrine HCl - Nasal Decongestant

Relief of:

- Headache • Body Ache • Sore Throat
- Nasal Congestion • Sinus Pressure • Cough

10 Softgels



# MULTI-SYMPTOM DAYTIME

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

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68210-4149
<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>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>POVIDONE K30</b> (UNII: U725QWY32X)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<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>	red (Orange to Red)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (OBLONG)	<b>Size</b>	21mm
<b>Flavor</b>		<b>Imprint Code</b>	512;A09
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-4149-1	1 in 1 CARTON	04/28/2021	
1		10 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	04/28/2021	

**Labeler** - SPIRIT PHARMACEUTICALS LLC (179621011)

Revised: 12/2023

SPIRIT PHARMACEUTICALS LLC